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Emergency Medical Services Systems as a Health Services Research Setting

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
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National Center for Health Services Research

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Abstract

This collection of papers was presented as a session of the Ninth Annual Meeting of the Society for Advanced Medical System. By illustrating a variety of different approaches to Emergency Medical Services (EMS) Research, it is intended to show the value of the EMS system as a setting for health services research.

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Foreword

In November 1977, the Ninth Annual Conference of the Society for Advanced Medical Systems (SAMS) was held in Los Angeles, in conjunction with the meeting of the Alliance for Engineering in Medicine and Biology.

The National Center for Health Services Research saw the SAMS meeting as an opportunity to alert an important segment of the health services research community to the challenge that exists in Emergency Medical Services (EMS) research. NCHSR staff members designed, organized and proposed to SAMS a panel of speakers, each of whom was conducting research in Emergency Medical Services. SAMS accepted the proposal and allotted three hours for the presentation of "Emergency Medical Services Systems as a Research Setting."

The speakers were selected to represent a wide variety of research methods and conceptual orientations being directed toward different kinds of research activities which can contribute to improvement of EMS systems. They also provide further evidence that EMS systems, as important components of health care delivery systems, provide frequent opportunities and excellent settings for examining significant health policy issues and testing theories of health-related behavior.

One additional feature becomes clear in the case of some of these papers: the development of methods and concepts prompted by the special needs and characteristics of the EMS setting may also contribute advances to the study discipline itself. A particular example is a provocative sociologic paper on the ways in which EMS councils use information and reach decisions. A complementary paper, presented at the meeting but to be published in *Medical Care,* dealt with the same processes from the point of view of a management scientist. Together, they suggest a revival of interest in exploring the behavior of complex organizations which may further the ability of researchers to examine many other social and political phenomena of this society, extending well beyond the health system.

As this presentation demonstrates, the Emergency Medical Services system offers an abundance of important topics to interest the trained researcher who has the tools needed to provide useful answers to significant methodologic and policy questions.

Gerald Rosenthal, Ph.D
Director

December 1978

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This collection of papers was presented at the Ninth Annual Meeting of the Society for Advanced Medical Systems, Los Angeles, California, November 9–12, 1977. The proceedings of the other sessions of that meeting will be published as *Prospects and Challenges for Advanced Medical Systems,* Harry E. Emlet, Jr., editor, published by Symposia Specialists, P.O. Box 610397, 1460 Northeast 129th Street, Miami, Florida 33161.

Technical and behavioral approaches to planning for Emergency Medical Services*

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Background

In an interesting analysis of recent developments in health planning, Bruce Vladeck identifies a fundamental issue. In his words:

> If the "technology" of health planning were substantially more advanced, it would make far less difference who sat on the governing body (of planning agencies), all that would matter would be the technical competence of the planners. In the absence of such an advanced technology, however, the planning process is inescapably political, and political considerations thus come to the forefront.[1]

While we do not necessarily agree with Vladeck that the technology of health planning is still in a relatively primitive stage, we find his comments useful in revealing a troublesome dichotomy. Health planning and system development has been a highly complex and frustrating enterprise for those who have participated in this activity.[2] Health planners have worked with two very different conceptions or models of planning. One of these models can be characterized as emphasizing the *technical* aspects of planning; the other conception of planning emphasizes the *social and political* aspects of the planning process.[3]

The technical approach to health planning conceives of planning as involving five basic steps: 1) establishing systematically, through research, the need for a health care program(s), 2) developing a plan to meet the identified needs—the plan includes a statement of program objectives, steps to meet the objectives, resources required, and alternative strategies for meeting the objectives with a rationale for selection from among the alternatives, 3) locating resources and applying these to the plan in a pilot phase, 4) evaluating the pilot test, 5) moving to full implementation or back to an earlier stage of development, depending upon the results of the evaluation.

In this technical conception of health planning, policy formulation is viewed as a relatively straightforward process by which needs are ordered in priority. Setting priorities is seen as being best accomplished by health professionals who call upon their "expert" knowledge.

The behavioral approach to health planning assumes a much more complex policy-setting process, based upon the concept of pluralism. Within this model health providers or professionals may have only one vote in setting policy. All of the other groups which have a special interest in health care are viewed as having a legitimate say in identifying needs and priorities and these groups are entitled to be involved in the policy process.

From this point of view health planning becomes primarily a political process which may or may not derive from data and proposals produced by technical experts. Representatives of various interest groups work out priorities, program objectives, resource allocation plans and fund raising procedures through both formal meetings and informal negotiations. Decision blockers must be identified and moved toward a position of consensus or planning could be halted. Within this model planners are expected to be versed in community organization techniques and to have political sensitivity and competence as basic skills.

Today both models of planning are alive and well. The "technical" model remains the ideal of many health professionals and academics. The "behavioral" model is seen by consumers and political leaders as reflecting the way things are in the "real world."

With the passage of Public Law 93-641, the National Health Planning and Resource Development Act, the behavioral model was recently given a legal expression. This Act establishes Health Systems Agencies (HSAs) which are responsible for health care planning on a regional basis. Technical planning by the Comprehensive Health Planning Agencies had not been successful; therefore, in the successor legislation Congress specified clearly the manner in which health planning would be carried out.

While authorizing the HSAs to collect and analyze data relative to the structure and operation of the regional health care system (i.e., to en-

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gage in technical planning), the Health Planning Act places the Health Systems Agency under the control of a governing board, the composition of which is carefully specified to include at least 51% (but not more than 60%) "consumers of health care services."[4] Consumers must be representative of the social, economic, linguistic and racial population, the geographic areas of the health service area, and the major purchasers of health care. Providers of health services, and public officials involved in providing or paying for health care, also must be represented on the governing board.

The proportion of individuals on the board from non-metropolitan areas must parallel the non-metropolitan proportion of the population in the health services area.[5] With the creation of such pluralistic structures, health planning becomes in actuality a complex political/social process.

We are not interested in telling those involved in health planning "What should be" or how they should ideally go about planning. Even if we were so inclined, who would listen? Rather, for a number of years we have been working towards the development of a more inclusive framework within which planners, consumers, health care providers and political leaders can formulate concepts about health planning.

With the passage of time, we have come to believe that health planners cannot effectively move communities toward the development of complex health care systems if they attempt to carry-out health planning through the perspective of either of the models outlined above. The most successful health planners combine the technical and behavioral approaches, probably intuitively.[6] We are trying to understand how they are doing this, to document these processes, and to develop a way of communicating this information to students, practicing health planners, providers of health services, consumers, and political leaders. Obviously, both models of planning encompass some of the real-world activities which we label health planning and system development; neither model, however, provides an adequate basis for actually conducting health planning or for carrying out research.

Put another way, if technical solutions to health planning and system development problems are to be accepted, the technical solutions must recognize human concerns, values and patterns of behavior. The most direct route between a human service problem and its solution, is usually blocked by hordes of persons who can think of many reasons, rational and subjective, for not proceeding. These blocks cannot be ignored by planners; they must somehow be circumvented if new health systems are to be developed and existing ones changed.

An illustration of the problem

Within nearly 300 planning regions throughout the United States, communities are attempting to plan for and build Emergency Medical Services (EMS) systems. Since the concept of an emergency care system is quite broad, a variety of persons are affected by planning and system development activity. In order for a community/region to make progress in building an EMS system, both technical planning and political planning are required.

This was not intuitively obvious at first in emergency care planning. One might wonder who, in any community, would possibly question the need for a highly efficient and effective system for responding to medical emergencies. As we have attempted to plan for and build these systems, however, it has become obvious that in some communities the utility of some, if not all, federally-prescribed components of the system have been seriously questioned on both rational and subjective grounds (e.g., advanced life support provided in mobile intensive care units, training attendants to the level of paramedics, hospital categorization, etc.). In many cases the battles have been intense, and a planning-system development process which many thought could be completed in a period of a very few years will more likely require a decade or more.

Let us illustrate using one of the system components required in a federally-funded program—the development of training plans and programs for basic and advanced emergency medical technicians (EMTs). Technically the procedure for developing such plans and programs is rather straightforward. It involves the following steps: 1) survey the community to identify the number and location of ambulance providers, the level of training and equipment, and the volume of ambulance runs for all companies, 2) estimate the demand for EMT training by asking ambulance attendants of their interest in additional training and using existing ratios indicating appropriate numbers of EMTs per 100,000 population, 3) identify training sites and specify courses, 4) identify and/or train persons to conduct training, 5) identify sources of funds (subscription, foundation, tuition, governmental), 6) schedule training and testing programs, 7) provide for periodic formal retraining and appropriate on-the-job training.

Through systematic interviewing in a number of communities, we have identified several behavioral/political problems which could have served as barriers to the implementation of this technical planning routine, and in fact did so. In many communities, volunteers (usually fire or fire-rescue squad members) respond to medical emergencies. These volunteers have often been dubious about the value of emergency medical technician training. They have argued that: 1) their time is being volunteered and no one should dictate to them the terms of volunteerism, especially a governmental or quasi-governmental agency, 2) it has not been demonstrated that such training is really effective in reducing morbidity and mortality, 3) this is a subtle attack upon the whole institution of volunteerism in this country. They believe that volunteerism strengthens our communities by providing the volunteers, their families and community members with a tangible activity upon which to build community identity. By attempting to dictate the conditions of volunteerism from outside the community, one weakens that incentive to do volunteer work and this weakens the community. Thus many communities have provided vivid illustrations of a confrontation between technical and subjective orientations.

Another problem in emergency medical technician training arises when physicians who provide medical instructions by radio, to emergency medical technicians during patient transport, do not really feel secure in so doing. This concern on the part of physicians, is in some cases, based upon the belief that the physician providing medical commands does not have sufficient control over the care provided by the EMT to assure adequate safety and quality.

This situation is thought to occur most commonly when physicians who provide medical command have not participated in the training of emergency technicians, and have therefore been denied an opportunity to observe the capability of the technicians in a training environment. Whatever the cause, such a "trust gap" between physician and technician will result in under-utilization of the capability of these allied health personnel.

Another problem also concerns the utilization of persons who have been trained, and arises when members of the public either fail to call for assistance when it is needed or call for help when it is not needed. This problem and the preceding one can adversely affect the morale of emergency technicians and can also result in a deterioration of their skills. Another dimension of the utilization problem relates to the popularity of EMT training. Some communities have trained far more persons than they need to meet their demands, and this also results in under-utilization and skills deterioration in some of those trained.

Methods to resolve each behavioral problem identified above can be addressed during the technical planning process. Usually this is accomplished by devising a formal mechanism for communications and complaints about the problem (e.g., a task force on training) and, if necessary, employing informal means to negotiate a resolution of the issues which emerge during planning.

For example, when the issue of volunteerism arises, additional ambulance systems might be organized, while providing opportunities for communication between volunteer companies and the newly established companies. Volunteers could remain at their current level of training, used as first responders, and made to feel a part of the larger system. This approach would openly acknowledge the fact that the voluntary organizations are deeply embedded in the social fabrics of many communities, can serve as useful actors in providing emergency care, and fulfill useful purposes other than the delivery of prehospital care. In some cases volunteers have been willing to undergo full training after appeals to either competitive values or community or personal pride.

The physician-paramedic utilization problem could be approached by including all physicians in the training sequence who may be involved in providing medical command. The consumer utilization issue could be addressed by organizing consumer education programs and having volunteers (consumers) participate in the design of these programs. Such efforts are intended to alter behavior which could destroy the development effort. When employed to reinforce the technical approach, behavior-related strategies significantly increase the probability of success of the training effort.

Description of a computerized game

The process of planning and instituting training programs for EMTs has been modeled as an interactive, computerized game. The game is designed to reproduce the important technical and behavioral components, and their interactions, of the process of planning and developing training programs. By playing this game, an individual can become sensitive to both technical and behavioral issues and can practice working out strategies to deal with these issues.

Another important value of the game is as a heuristic—an aid in the development of a theory of planning which incorporates both technical and behavioral models. Working on the model has required that operations researchers and behavioral scientists define and quantify the behavioral issues which interfere with technical planning and identify feasible strategies for their resolution.

The model development process is a critical step in this type of research because it insures that the political and social structures are understood as completely as possible. The design of a model forces the investigators to break the system down into its component parts and to hypothesize the nature and type of relationships which exist between each of the components.

When the model is used for the training game, the player views the system from the perspective of the local EMS coordinator or regional director. The objective is to develop and maintain a high level of training among emergency technicians within the community. The community is divided into four sectors or spheres of interest- consumer, transportation provider, political and medical. The EMS coordinator or planner (player) must utilize available resources to establish and maintain good relationships with each of the community groups. The nature of these relationships influences the demands for each level of training as well as the availability of different sources of funds.

Funds can be obtained through any of four sources: foundation grants, governmental grants or contracts, tuition and subscription. The probability of obtaining funds depends on the level of the community relationship with each of the four sectors and on the amount of funding requested.

The EMS coordinator (player) has two types of resources at his disposal—funds and human manpower resources. Funds can be used to manage a staff of professionals, to obtain additional funding, to train emergency technicians and/or instructors and to obtain information about the system so that intelligent decisions can be made. The coordinator must also acquire a staff, schedule classes, train instructors, seek outside funding, improve community relationships, and recertify technicians. Training can progress from Red Cross (first aid) through three advanced levels called EMT 1, EMT 2 and Paramedic. The demand for each level is influenced by the number of personnel trained at the next lower level and the nature of the individual community relationships.

The game sensitizes the player to the issues involved in planning, developing, and managing the training system. In order to successfully train EMTs the player must become aware of the individual system components and realize that the training subsystem exists in a highly complex and interrelated environment. For example, since obtaining governmental grants requires not only strong political relations but also positive consumer support, the level of consumer relations is tied to political relations. The demand for training depends to some extent on the strength of medical relationships. Neglecting one component of the community sector will result in failure to effectively develop a training program. The player is given no knowledge of any of the underlying relationships, nor how they affect each of the components. The player must "purchase" all information concerning the demands for each level of training and the level of each community relationship. The accuracy of the information which the player receives depends on the amount of funds he allocates for this purpose.

Figure 1 shows a schematic diagram of the EMT game. Four component sections of the game are illustrated: the physical system, the funding system, the community relations system and the management system. The physical system is concerned with the movement of people through the training process. Movement between levels is determined by the availability of people willing to be trained and the availability of resources (instructors and money). The semi-circular loops in the Figure denote training delays. Movement within levels is represented by those trained at a particular level and not desiring further training, and those who are demanding further training. These flows are affected by the relationships with the four community sectors, how many have been trained at a higher level, the need for recertification, and attrition rates that reduce the number of trained personnel.

As discussed, funding is obtained from one of four sources. Funding may also be affected by the passage of legislation, considered an extraneous event in this model. The availability of funding is determined by the relationships with the four community sectors; in addition, however, resources must be allocated to secure funds.

The community relations system consists of the four sectors discussed earlier. As noted, resources must be assigned to maintain these relationships. The state of the medical relations also determines the availability of instructors. Relations can be improved by increasing the involvement of the members of the sectors or interested groups through task forces and committees. All four relations are interactive, so that increasing one will have some effect on the others.

The management system consists of four types of resource allocation decisions: 1) hiring/firing personnel; 2) acquiring and utilizing instructors; 3) scheduling classes; 4) acquiring information.

An initial scenario is generated by the computer to start the game. The player knows the initial conditions for the four community-sector relations, the number of instructors, the number of attendants trained at the Red Cross level, and the number of resource units available.

Figure 2 portrays the initial start of the game. The population of the community is 983,143, there are 1,915 attendants trained at the Red Cross level; two instructors are available; the decision maker has $25,951 resource units at his disposal. Community relations initially are very good (high) for the consumer sector, good (medium-high) for the transportation (provider) sector and fair to poor (medium-low) for the political and medical sectors.

Figure 2: EMT training game at start

```
Enter real time limit (minutes) = > 30
Enter simulation time limit (weeks) = > 300

Population.......................................... 983,143
Attendants at Red Cross level ...................... 1,915
Instructors ............................................... 2
Resource units ................................... 25,951

Relations with communities:

---------------------------------------------------------
        Community                   Relation
---------------------------------------------------------

Political                       Medium-low
Consumer                        High
Medical                         Medium-low
Provider                        Medium-high
```

Figure 1: Flow chart of Emergency Medical Services training decision process

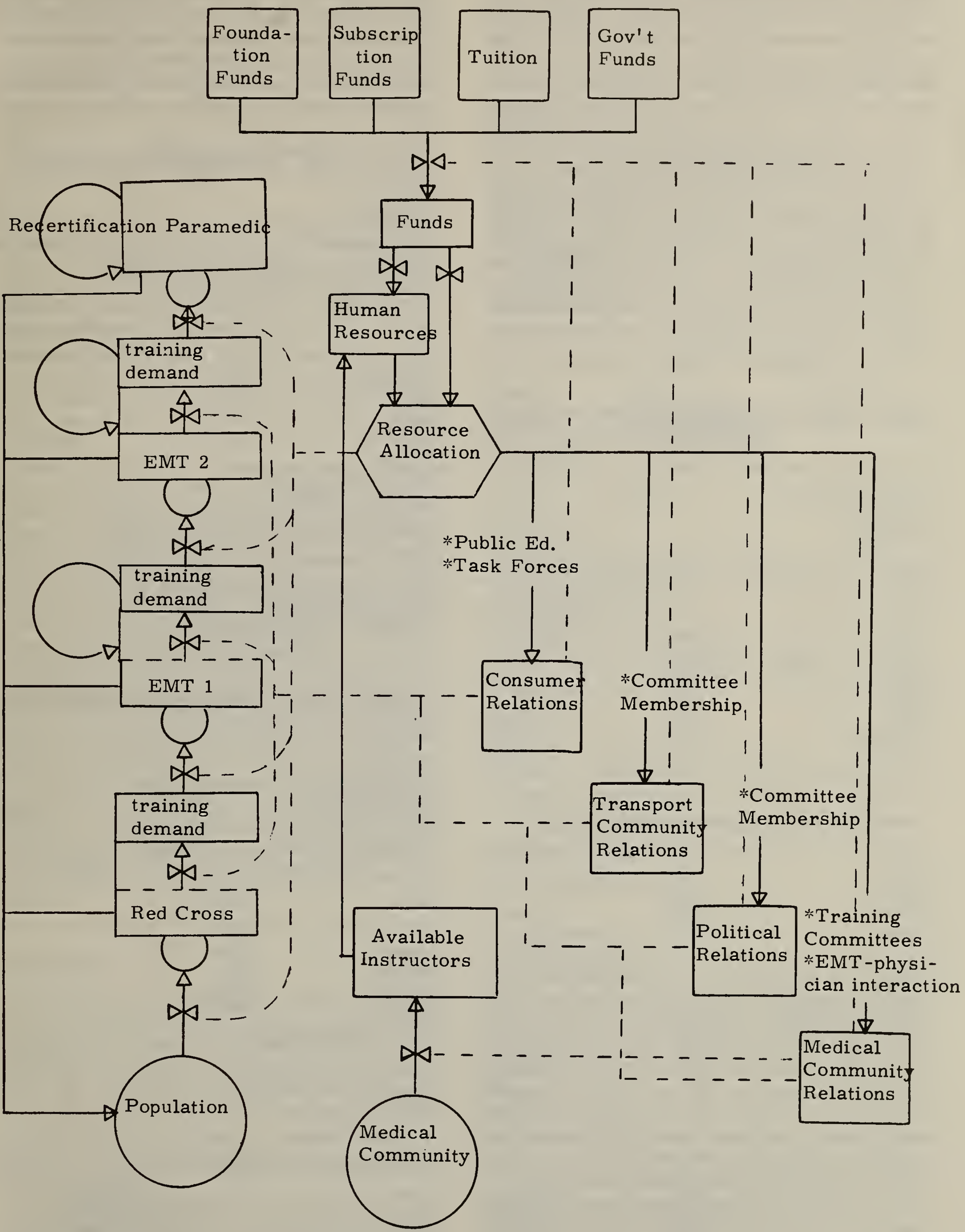

Figure 3 shows that the decision maker has paid to obtain additional information on the number of EMT's trained and demanding training at each level and the quality of community relations. The 1,945 Red Cross trained personnel provide a pool for EMT 1 training. Community relations range from a high value of 8.185 for consumers to a low of 2.621 for political leaders on a scale of 0 to 10. However, recall that the accuracy of this information is a function of the amount of resources paid by the planner to determine these levels.

Figure 4 shows the game during the fourth week. The data indicate that 115 Red Cross trained personnel are demanding EMT I training. The decision maker schedules three classes at a cost of $3,000 each. The computer indicates that an insufficient number of instructors are available. A decision is made to train two additional instructors at a total cost of $5,000. It will require eight weeks to train these instructors.

Figure 3: EMT training game; initial request for information

```
Enter info. type, units paid: = > help

Information types are:
(1) Attendant
(2) Relations

Enter info. type, units paid: = > attendant 800
--------------------------------------------------------
                                        # Demanding
  Level                   # Trained      training
--------------------------------------------------------
Red Cross                   1,945           0
EMT 1                         0             0
EMT 2                         0             0
Paramedic                     0             0

Enter info. type, units paid: = > relations 750
--------------------------------------------------------
  Sector                 Relations
--------------------------------------------------------
Political                  2.621
Consumer                   8.185
Medical                    4.916
Provider                   4.641
```

Figure 5 indicates that all but $7,400 of the original $25,951 has been spent by the ninth week. Political relations have improved significantly while the other relationships appear to have remained the same. Again the accuracy of this information is a function of the dollars expended. The two new instructors are available at the twelfth week, and two more EMT classes are scheduled during the thirteenth week. These classes will graduate in the twenty-fifth week.

The value of good information can be illustrated readily. If, during the tenth week, the player requests data on the relationships with the four sectors, but does not commit resources for obtaining this information, the resultant data would indicate that the governmental relationship was very high (9.194), the consumer was high (8.375) and medical and provider were above average (6.820 and 6.404 respectively). Acting on this information, the player might then decide to commit no further resources to improving governmental and consumer relationships, but rather seek funding from sources which depend on these relations. In reality

Figure 4: EMT training game at fourth week

```
Time: 4.0
# of instructors .........................           2
Available instructors ......................          2
Units remaining ..........................     24400.87

Enter info. type, units paid: = >attendant 800
--------------------------------------------------------
Level              # Trained      # Demanding training
--------------------------------------------------------
Red Cross            1,946               115
EMT 1                  0                  0
EMT 2                  0                  0
Paramedic              0                  0

Enter info. type, units paid: = >

Command = > Class

Enter class type and # of classes = > EMTI 3

3 EMT1     Classes costs     3300.00 units

Not enough instructors.      2 available
Do you wish to add more?       > Yes
How many?    (2500.00 units/instructor)      > 2

*2 Instructors are being trained at a cost of 5000.00
```

Figure 5: EMT training game in ninth week

```
Command = > information

Time: 9.0
# of instructors ........................            2
Available instructors .....................           0
Units remaining .........................       7400.87

Enter info. type, units paid: = > relations 500
--------------------------------------------------------
Sector               Relations
--------------------------------------------------------
Political              8.399
Consumer               8.042
Medical                4.873
Provider               4.089

Enter info. type, units paid: = >

Command = > Advance 4
Time: 12.; 2 new instructors
Time is 13.

Command = > class

Enter class type and # of classes = EMT1 2

2 EMT1                                Classes cost
                                        2200.00 units
2 EMT1                                Classes scheduled.
30 Attendants per class.              Total: 60.
Graduation time:                      25.
```

this would be a bad decision, since during the tenth week the actual governmental and consumer relations were significantly lower than reported (5.813 and 4.230), while medical was higher (7.882) and provider was somewhat lower (5.289). Consequently, any decisions to seek funds at this time would be unwarranted and a needless expenditure of resources, the sector relationships are too low for successful funding. Further, neglecting improvement of sector relationships, even at this early point, would lead to "sub-optimal" results since these factors will affect the entire play of the game.

Figure 6 indicates that government funding is still unavailable; however, subscription funds were obtained during the forty-fifth week ($28,876). Also at this time four classes of EMT I's are graduated. However, only 38 out of the 120 who started graduated. Four more classes of EMT I are immediately scheduled. At the forty-ninth week, the available resources have increased to $29,330, ten instructors are available, 287 EMT I's have been trained with 113 demanding EMT II level training.

Figure 7 is the final output at the end of this session (59 weeks). A total of $19,095 remains unspent; 22 EMT II's and 506 EMT I's have been trained and remain in the system; 1,603 Red Cross level personnel exist with 1,413 demanding EMT I training. Political relationships have improved significantly, medical and provider relations have improved by a small amount, while consumer relations have deteriorated somewhat.

Thus, in playing the game the planner is required to do technical planning within a social/political milieu. Failure to deal with the social/political problems will lead to insufficient support within the community for the training effort.

As the field research continues, more behavioral variables will be identified, classified and added to the game. The game will be expanded to bring in other segments of the EMS system and to allow for multiple players with conflicting objectives and values.

Conclusions

We believe it is possible to provide health planners and system developers with technical skills and political sensitivities required if one is to work within our pluralistic, democratic social/political milieu. We hope to be able to move from an identification and understanding of behavioral issues specific to EMS to a delineation of problems, and strategies for their resolution, which are generic to health planning.

It is worth emphasizing that subjective or behavioral barriers to change are not in themselves to be viewed as "good" or "bad." These resisters may serve as a valuable brake on technical solution which, though efficient, may introduce changes which are inconsistent with human needs, priorities, behavior styles and values. Technical planning, if it is to be useful and successful, must be consistent with, and continually aware of, the styles, values, priorities and needs which prevail in

Figure 6: EMT training game in forty-ninth week

```
Command = > Funding

Enter Funding Type = > government
Not permitted to reapply for this funding type yet

Command = > advance 8
**Receiving subscription funds. Units added: 28876.20
Time: 45.
**Class graduation
4 classes of EMT1                    Trainees
    38. Graduate out of              120
Time is 49.

Command = > class

Enter class type and # of classes = >EMT1 4

4EMT1              Classes costs              4400.00 Units

4 EMT1             Classes scheduled.
30 Attendants per class. total: 120.
Graduation time:     61.

Command = > information

Time: 49.0
# of instructors .........................              10
Available instructors ...................               0
Units remaining .........................        29330.65

Enter info. type, units paid:            = > Attendant 990
------------------------------------------------------------
Level              # Trained      # Demanding training
------------------------------------------------------------
Red Cross             1726              1393
EMT1                   287               113
EMT2                     0                 0
Paramedic                0                 0
```

Figure 7: EMT training game; end of play

```
Command = > Stop

Real Time Limit Exceeded.

Time: 59.0
# of instructors .........................              10
Available instructors ...................               0
Units remaining .........................        19095.65
------------------------------------------------------------
Level              # Trained      # Demanding training
------------------------------------------------------------
Red Cross             1603              1413
EMT1                   506               180
EMT2                    22                 1
Paramedic                0                 0
------------------------------------------------------------
Sector             Relations
------------------------------------------------------------
Political          9.683
Consumer           7.496
Medical            5.150
Provider           5.801
------------------------------------------------------------
```

each community. Without this sensitivity, technical planning will almost certainly be ignored, undermined or circumvented, leading inevitably to failure and loss of faith in health system planning and development.

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Viewing EMS as a system*

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Introduction

Legislative bodies and administrators, both public and private, continually make decisions about the allocation of scarce resources among the myraid of competing needs and demands. Emergency medical services (EMS) are a response to one kind of public need. Historically, EMS developed in a topsy-like manner in an environment of uncoordinated jurisdictions, economic forces and advances in medical knowledge and practice. They were provided by largely uncoordinated aggregations of public and private organizations. Understandably, they provided uneven results, experienced spiraling increases in demands and costs, and engendered dissatisfaction in both patients and providers. Except for a few interested public officials and some dedicated medical practitioners and public safety agencies, EMS was largely ignored until the last decade.

In the mid-1960's, the inadequacies of existing EMS[1] and the possibilities for translating advances in medical knowledge into new forms of EMS[2] began to be publicized widely. The federal government responded to these needs and opportunities with the passage of the Highway Safety Act of 1966. This legislation provided funds for the development of some new tools for the planning and evaluation of EMS systems and for introduction of some experimental forms of EMS systems in a few regions of the country. EMS in most of the country, however, continued to lag substantially behind the known state-of-the-art. The Emergency Medical Services Systems (EMSS) Act of 1973 was the next major milestone. It set forth guidelines and requirements for regional EMS systems and provided funding for the planning, establishment, expansion, improvement and operation of such regional EMS systems. It also provided funding for research on EMS topics, including planning and evaluation.

A critical problem remained, however. Simply stated, it was that the availability of funds for upgrading EMS from various levels of government and private foundation has far exceeded the capacity to use such funds effectively. While well intended, the majority of efforts to improve EMS continue to suffer from a variety of weaknesses. These weaknesses include the lack of a conceptual framework, the lack of systemwide performance criteria, a tendency toward isolated improvement of elements of EMS, and an emphasis on either the technical or the socio-political side of the planning process to the exclusion of the other. Paradoxically, several bodies of knowledge and experience are available and applicable to a unified approach to the planning of EMS. These include:

1. Concepts and methodologies for the design of complex, socio-technical systems.
2. Technical knowledge and capabilities regarding critical care medicine, transportation, communication, public education, training and the coordination and direction of complex service systems.
3. Planning processes which utilize many individuals in the identification of problems, development of solutions and implementation of solutions.

Concepts and methodologies of the systems approach

At one time or another all of us deal with problems by immediately looking for a solution, picking the first one that comes to mind and implementing it. As we have all experienced, this approach may solve the problem or it may produce a more serious problem than the one we started with. The systems approach is a way of forestalling this tendency when dealing with important problems. It forces us to conceptualize freely in defining the problem, developing a rich set of potential solutions, selecting the most attractive of the alternatives and implementing it.

Conceptualizing EMS. A frequent question is what is the EMS system? Given the manner in which EMS have evolved in this country as an ad-

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*The work in progress, which is described, has been funded by the National Center for Health Services Research (HS 01923-02).

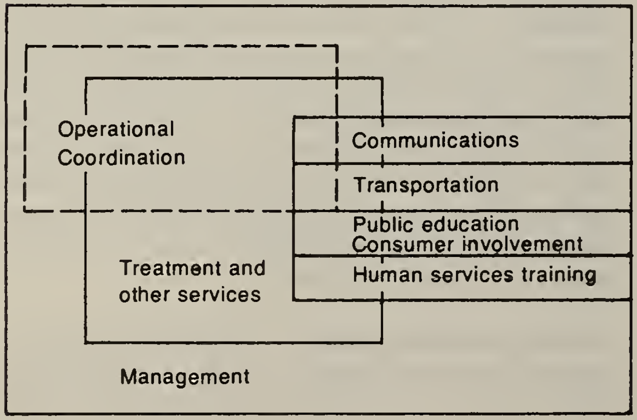
junct to or piggybacking on the larger health system and public safety agencies, this is not an unexpected question. It is a maxim of the systems approach that one is free to define a system in whatever way is judged appropriate to the situation. Thus, in terms of the agendas of congressmen and senators, it was appropriate to define a "complete" EMS system in the EMSS Act of 1973 as consisting of fifteen components. There are a mixture of elements (*e.g.*, facilities and mutual aid agreements), functions (*e.g.*, communication and training of personnel) and policies (*e.g.*, consumer participation in decision making and accessibility to care without prior inquiry as to ability to pay).

The permissiveness of the systems approach does not mean that there are no guidelines for defining systems for specific purposes. For designing systems it is a maxim that they should be conceptualized in functional terms, not according to common ways of doing these functions. While preserving all of the options for varying the numbers, specific forms and linkage of conventional elements, the functional approach enables additional options to be generated through the introduction of new elements. These additional options serve to raise the attainable level of performance of the EMS system, whatever its eventual design.

Figure 1 presents one conceptualization of EMS in functional terms.[3]

The notion of a systemwide management function for EMS is in contrast with the more common lack of coordination among and independent natures of the activities of separate political jurisdictions. A single entity with authority to plan and manage the operations of the EMS system is needed. Admittedly such authority is in conflict with the perogatives and preserves of local governments. This conflict should be resolved in favor of some kind of systemwide management entity with safeguards for the rights of local governments that have given up "home rule" to gain the benefits of a cost-effective regional EMS system.

Figure 1: Interrelationships among EMS functions



The *raison d'etre* of EMS is the maintenance of life and avoidance of structural and functional losses of limbs and organs among critically ill and injured persons who are precluded from using the primary health care system because of factors such as their location, the day or time, ability to pay, etc. This mission establishes the primary criterion for the design of EMS systems.

The maintenance of life and avoidance of losses are influenced by a number of factors including the nature, extent and severity of illness or injury and the victim's constitution. In terms of the EMS system itself, however, the factors which influence patient outcomes and can be changed by the designers, are the kinds and timings of treatments. Thus, treatment is the core function. It is the function around which the entire system is designed. The other EMS functions (*viz*, communications, transportation, public education/consumer involvement, and human services/training) are supportive. They contribute to the attainment of the overall EMS objective of preserving life, limb and organ by facilitating the activities of the core function of delivering treatment. The requirements and specifications for the supportive functions are derived from the design concept which is chosen for the treatment subsystem. It is only when we have decided what interventions are to be delivered in what ways and in what time frames that we can define what supportive activities are needed. Consider for example, the differences in the communication and transportation requirements for a treatment subsystem in which the patient goes to the provider of treatment and one in which the provider of treatment goes to the location of the patient.

Developing candidate design concepts. Conventional wisdom and traditional modes of performing a function pose serious obstacles to the identification of a rich set of alternatives. A useful approach for generating potential candidate designs is to use the morphological method.[4] This method utilizes the structure of the problem to identify all possible solutions and is limited only by the problem definition. It has been applied to problems ranging from the study of languages to astrophysics. The method is quite simple. An exact statement of the problem is made and the important characteristics upon which the solution depends are identified. The qualities or values that each characteristic can have are then identified. The set of possible solutions consists of all possible combinations of the characteristics in terms of the qualities or values that each characteristic can have.

In an application of the morphological approach to the design of only the treatment and supportive transportation subsystems, 630 unique design concepts were generated.[5] With such large numbers, means must be found for reducing to a manageable set the number of possible solutions which must be evaluated in detail. In this example, the use of three simple policy guidelines (for which there was broadly based support among communities, local governments, and provider/professional organizations) pared the total list of 630 down to only three surviving candidates.

Evaluating candidate design concepts. Four kinds of methodologies are required to provide the kinds of predictions needed to select a single EMS system design concept for implementation. These are models for predicting:

1. The nature, geographical and temporal distributions of the demand for various EMS.
2. The operational characteristics (including the kinds and timing of treatments) with which each candidate design concept would respond to the predicted volume and pattern of demand.
3. The impact on the health status of the target population of delivering treatments of the kinds and with the timings associated with each design concept.
4. The costs (both capital and operational) of each candidate design concept.

Three of the four kinds of methodologies are quite well developed. In fact the numbers of available models for predicting demand, operational performance and costs in EMS are too large to acknowledge individually. It is only in the area of predicting the impact of alternative ways of organizing and delivering EMS on the outcomes for patients that we lack adequate capabilities. In the absence of such a capability, the most frequent approach to improving EMS in a community has been that advocated by an influential individual or group. As a consequence, the results have been dictated largely by chance.

The following section will describe one effort to contribute to filling this void.

An empirical study of the influence of the kinds and timings of treatments on patient outcomes

Outcomes for patients. There are numerous outcomes for patients which can be used to evaluate the impact of a change in medical services on the health status of the population to be served. The most frequently employed are mortality and morbidity or some combination thereof.[6]

The use of mortality as a measure of health status is not as straightforward as it may appear. What one really wishes to measure is avoidable mortality, or those deaths that are judged to be preventable with appropriate, state-of-the-medical-arts care.[7] All prevented deaths, however, are not necessarily judged to have the same "value." A prevented death from heart disease in an elderly person may result in five to ten additional years of life with significant alterations in the "quality" of life. A prevented death from accidential poisoning in a young child may result in an expected sixty to seventy years of life with no reduction in "quality."

The concept of the value of a human life has been introduced to quantify these kinds of differences in prevented deaths. The value of a human life can be quantified in terms of future earnings, future earnings less consumption, the per capita expenditure to prevent death, etc., and be based on demographic and socioeconomic characteristics.[8, 9, 10, 11] Until weightings that appropriately reflect the social and ethical issues and the "quality" of life are incorporated, these are not satisfactory quantitative measures of the value of a human life. It is argued here, therefore, that the best approach is that of simply predicting the change in mortality that is expected to result from the introduction of any particular change in medical services. Decision-makers can then subjectively value the trade-offs between that number and, if desired, any set of demographic or other descriptors of the persons whose lives are expected to be saved and the costs to implement and operate the change.

Other measures of health status such as morbidity, permanent structural loss or impairment of a limb or organ, and cosmetic disfigurement, are fraught with even greater methodological problems than those inherent in the use of mortality. Regardless of the value placed on the life that was lost, a death is a death. In contrast, as the processing of insurance and workman's compensation claims has demonstrated, it may be difficult even to establish whether or not a functional loss has occurred. The evaluation of the extent of the loss and of the value to be attached to it is even more difficult.

Project description. The primary objective of the current project is to examine empirically the influences of the kinds of, and elapsed times to, medical treatments on mortality, morbidity and disability of EMS patients.

Two of the major methodological problems in studying such relationships are taxonomical in nature, namely how to classify patients in terms of the nature and severity of their pathophysiologies.[13] The classification scheme for the nature of the patient's pathophysiologies must be exhaustive of illnesses and injuries which are threatening to life, limb, and organs, and yet limited enough in number to permit empirical study. Neither conventional descriptors, such as the name of a disease or the nature of an injury, nor existing classification schemes which have been developed for other purposes, are suitable. A central element of the project, therefore, has been the development of a classification scheme which is appropriate. The new classification recognizes that the final pathway to death of the individual or of a limb or organ is the cessation of cellular metabolism. A medical emergency exists whenever the functioning of the cellular metabolism system is severely compromised. This can happen because of changes within the cellular metabolic system. It can also happen because of compromises in the functioning of either or both the ventilatory system and blood gas transport system, which respectively maintain an aerobic environment for, and supply "fuel" to, the cells. With the aid of a large panel of medical specialists, a total of thirteen conditions, which are based on pathologic situations and the anatomic levels at which they occur, were identified as an exhaustive listing of how the functioning of the three body systems may be impaired. These are shown in Table 1.

Table 1: Pathophysiologic/anatomic classification scheme

Ventilatory system

1. Loss of external oxygen supply
2. Airway obstruction
3. Lung dysfunction
4. Reduced bellows action-mechanical
5. Reduced bellows action-neurogenic

Blood gas transport system

6. Reduced blood oxygen capacity
7. Low blood volume-hemorrhage
8. Low blood volume-fluid loss
9. Low blood volume-abnormal peripheral distribution
10. Pump defect-electrical
11. Pump defect-mechanical
12. Disruption of local circulation

Metabolic system

13. Disordered cellular metabolism

Each of the thirteen conditions is uniquely identified by a set of rules which employ indicators such as history, physical signs, laboratory results, interventions and diagnoses. A patient may have more than one condition. Multiple conditions may compromise one, two, or all three body systems.

Three levels of severity were defined: critical, potentially critical and other. Only those classified as critical and potentially critical were included in the study. Critical patients are those who, without treatment that is appropriate to their condition(s) and timely, have a possibility of dying or of incurring physical or functional loss of limb or organ. Potentially critical patients are those who, without treatment that is appropriate to their condition(s) and timely, have a possibility of becoming critical. The level of severity is evaluated separately for each of the three body systems by a set of indicators.

Specially trained Registered Nurses, with extensive critical care or emergency department experience, screened emergency department patients and collected data from medical records of twenty-eight hospitals in Los Angeles and Ventura Counties. Patients were tracked from the onset of symptoms or occurrence of injury to 45 days after the date of their emergency department admission. The two classification schemes were used to sort patients and to evaluate severity.

The onset of potential criticality and of criticality were estimated as the first time that an indicator or set of indicators emerges which satisfies one of the criteria for the respective level of severity. The medical interventions that are appropriate to each of the thirteen conditions have been identified. For each condition, each appropriate intervention has been designated by the medical panel as restorative (i.e., can restore the functioning of a compromised system to an adequate level) or supportive (i.e., can slow or arrest the rate of degradation of the functioning of a compromised system or can enhance but not restore such functioning). All interventions that are appropriate to each condition into which the patient has been classified, and the times of administration, were recorded. Finally, the health status of the patient was evaluated 45 days after emergency department admission.*

Preliminary results. A total of approximately 4100 cases have been collected. Since the major emphasis has been on critical patients, about 3200 are critical cases and the remainder potentially critical ones. The following preliminary results are based on the first 1950 critical cases.

The influence of the nature and timing of treatment on the survival rate of critical patients is being investigated at three levels of aggregation: all cases, systems, and individual conditions. Several general findings are important for planning:

1. The proportion of "critical" patients (as defined by in the project) is only about 1.5 percent of all emergency department patients. The original model estimate, made by emergency physicians who were familiar with the project's method of evaluating severity, was that 10 percent of emergency department patients were critical.
2. The interval between the onset of criticality and

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*For example, the appropriate interventions for the condition of airway obstruction were defined as: (1) antibiotics, (2) antidotes/antagonists, (3) bronchodilators, (4) oxygen, (5) anti-seizure drugs, (6) steroids, (7) oral-esophageal or endotracheal airway, (8) physical displacement or removal of airway obstruction, and(9) airway surgery.

the first restorative intervention for any condition in the critical system(s) provides the best measure of the treatment delay. In this context, "best" means that, among the various measures of treatment delay that were examined, this one is the most strongly related to survival rate.

3. The efficacy of restorative interventions is shown by the fact that the survival rate among the 85 percent of all critical patients who received at least one restorative medical invervention for their condition(s), was 70 percent. For the 15 percent who received interventions that were appropriate, but not restorative, for their conditions the survival rate was only 19.5 percent.
4. Additional characteristics must be employed to identify the sub-population among critical patients for which survival is highly sensitive to treatment delay. Two characteristics appear to be most useful for this purpose:
   a. *Symptom-to-criticality interval.* This is the time from the beginning of symptoms or the occurrence of injury to the point at which the patient became critical. It is a measure of the rate of change in severity.
   b. *Symptom-to-contact interval.* This is the time from the beginning of symptoms or the occurrence of injury to first contact with the EMS system (either a mobile EMS unit or emergency department). It is a measure of lay perception of the urgency with which treatment is required.

Figure 2 shows the influence on survival of the time from the onset of criticality to the first restorative intervention for all cases in which the patient became critical within 30 minutes. Only a subpopulation, consisting of those who also first contact the EMS system within 15 minutes, has an identifiable sharp drop in survival rate with increasing delays to treatment. There are undoubtedly other patients in the rest of the critical population whose survival was highly sensitive to the time of treatment. To date, however, we have not been able to identify them. An examination of the composition of the highly time-sensitive subpopulation reveals that it appears to include higher proportions of cardiac arrests, arrythmias and drownings and a lower proportion of trauma cases and myocardial infarctions than the total population of critical patients.*

Beyond a treatment delay of forty minutes, the survival rate becomes constant for those contacting the EMS system within 15 minutes. It is also independent, or almost so, of the treatment delay for those contacting the EMS system more than 15 minutes after the onset of symptoms or occurrence of injury. This suggests that there is a small portion (about 1 in 1000) of emergency patients whose survival is highly dependent upon the rapidity with which they receive restorative treatments. This group is also highly salvageable and has a survival rate of about 90 percent for those receiving immediate treatment. The EMS system appears to recognize the extremely critical nature of these patients and administers treatment accordingly.

The criteria (viz, rapidity of becoming critical and rapidity of contacting the EMS system) which were used to isolate a subpopulation rich in highly time sensitive patients, are not perfect. For those patients who differ from the highly sensitive ones only in terms of the treatment delay, the response of the EMS system appears to have been more conservatively managed in terms of the timing of treatment. Those with longer delays in contacting the EMS system appear, as a group, to have been less critical. During the first hour of criticality, the survival rates of those contacting the system between 15 and 29 minutes and in 30 minutes or longer are roughly 76 and 82 percent respectively. The near constancy of these survival rates suggests an approximate matching of the timing of treatment with criticality.

Figure 2: Relationship between time to treatment and survival rate for critical patients with any condition or combination of conditions.

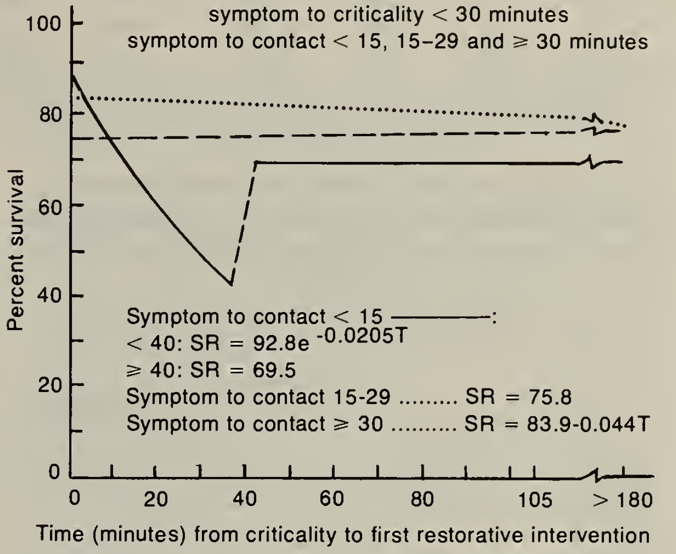

Table 2 summarizes the analyses for the aggregation of all conditions. At the level of systems, there are enough cases to perform meaningful analyses for only two of the three systems. For the ventilatory and blood gas transport systems, highly time-sensitive subgroups can be identified on the basis of only the symptom-to-criticality interval. For the ventilatory system, the region of a statistically significant inverse relationship between the

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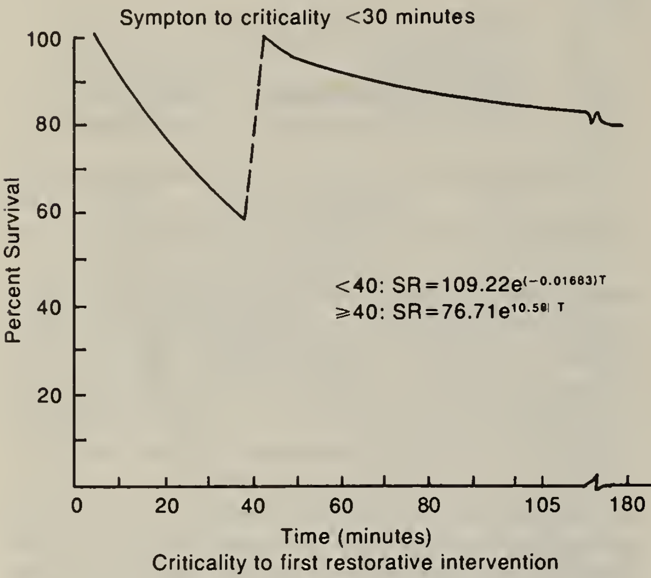
*Without a firm diagnosis of myocardial infarction, patients are classified according to symptomatic evidence either to cardiac arrest or arrhythmia consistent with ICDA procedures.

Table 2: Summary of statistically significant relationships between survival rate and time from criticality to first restorative intervention for the entire sample population of critical patients and various subpopulations thereof

Population of patients in terms of time intervals (minute)			*Sample size*	*Estimated proportion of*		*Survival rate (SR) as a function of the time in minutes from criticality to first restorative intervention (T)*			
						With restorative intervention		*Without restorative intervention*	
Onset of criticality	*EMS system entry*	*Critical to first restorative intervention*	*Total (with restorative intervention)*	*All emergency department patients*	*Critical emergency patients*	*Mean SR*	*Predictive equation*	*Proportion of (sub) population*	*Mean SR*
All	All	All	1950 (1652)	1.4%	100.0%	70.0%	SR=70.0	15.3%	19.5%
<30	All	All	774[1] (688)	.59	42.1	—	— −0.150	11.1	15.1
<30	All	<40	243	.18	13.2	73.1	SR=104.6T	—	—
<30	All	≥40	445	.34	24.2	75.9	SR=75.9	—	—
≥30	All	All	1066[1] (877)	.81	57.9	66.6	SR=66.6	17.7	20.6
<30	<15	All	272 (229)	.21	14.7	—	— −0.0205T	15.8	12.0
<30	<15	<40	147	.11	8.0	70.8	SR=92.8e	—	—
<30	<15	≥40	82	.06	4.5	69.5	SR=69.5	—	—
<30	15-29	All	165	.13	9.0	75.8	SR=75.8	10.9	5.6
<30	≥30	All	294	.22	16.0	77.3	SR=83.9−0.044T	8.5	28.0

[1] Do not sum to the total sample size for all critical patients because of cases that were missing times of symptoms.

Figure 3: Relationship between time to treatment and survival rate for critical patients with conditions solely in the blood gas transport system.



treatment delay and survival rate extends only through the first twenty minutes of criticality. For the blood gas transport system, this region extends through the first forty minutes as was the case for the aggregation of all conditions.

Figure 3 and Table 3 present the results for the blood gas transport system. The relationship for this system differs from that for the aggregation of all conditions in that it has two regions of falling survival rate with increasing treatment delay. More sharply than for the aggregation of all conditions, this suggests two distinct subgroups. In Table 3 it should be noted that there is a difference, within each portion of the curve, between receiving appropriate but nonrestorative interventions and receiving restorative interventions.

At the level of individual conditions, most of the categories for which there were enough cases in the initial sample to attempt analysis showed patterns that are suggestive of the same general natures as those for the aggregation of all conditions and for the two systems. At this level, however, few statistically significant relationships have been found because of limited sample sizes.

The relationships which have been presented must be viewed with several limitations:

1. They are based on something less than two-thirds of the total sample of critical patients.
2. They are based on the observed relative frequencies with which patients were classifiable into the various categories. These relative frequencies may be different in other parts of the country.
3. The observed relative frequencies have not yet been corrected for the bias which has been introduced because the proportions of usable cases (*viz,* those with complete information) varied from category to category.

Because of these limitations, these preliminary results should be viewed as only suggestive of the general nature of the influences of time-to-treatment on the survival rate among highly time-sensitive patients.

Analyses at all levels of aggregation are currently underway for the entire samples of both critical and potentially critical cases. In the latter analyses, the relationship of interest is that between the treatment delay and whether or not potentially critical patients become critical.

Table 3: Summary of information regarding transport cases

Population of patients				Estimate proportion of:		
In terms of intervals (mins)						
Symptom-criticality time	Criticality time to intervention	In terms of intervention type	sample size	All emergency department visits	Critical patients	Survival rate
<30	<40	First	77	.06%	4.2%	63.6%[2]
<30	<30	First restorative	22	.02%	1.2%	77.3%[2,4]
<30	<40	Difference[1]	55	.04%	3.0%	58.2%[4]
⩾30	<40	First	235	.18%	12.8%	49.7[3]
⩾30	<40	First restorative	77	.06%	4.2%	63.6%[3,5]
⩾30	<40	Difference[1]	158	.12%	8.6%	43.0%[5]

[1] The difference between the number of patients who received their first intervention with 40 minutes of criticality and those who received their first restorative intervention in the same elapsed time to treatment interval.

[2] Difference in survival rates is statistically significant at the 0.20 level

[3] Difference in survival rates is statistically significant at the 0.05 level

[4] Difference in survival rates is statistically significant at the 0.10 level

[5] Difference in survival rates is statistically significant at the 0.01 level

Together with other research on factors influencing the benefits of EMS, the results can be linked with other predictive models to predict in advance the consequences that would accrue from the implementation of any contemplated changes. While not eliminating the need for pilot studies in specific applications to verify predictions, these evolving tools will permit the most advantageous options to be identified. For example, an earlier, more limited effort of this type showed that the differences in survival rates of critical myocardial infarction patients handled by paramedics and by EMT-1, which were observed in an extensive pilot study, could have been predicted very closely.[14]

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Studying costs and benefits in EMS systems

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The Emergency Medical Services Systems Act of 1973 included a requirement for "periodic, comprehensive and independent review and evaluation" of emergency services in any community receiving funds under the Act. [1] This requirement was interpreted to mean that EMS systems had to evaluate only their quality and effectiveness. While effectiveness is important, a complete evaluation must also consider costs. Cost-effectiveness analysis has recently been applied in several medical areas—to surgical procedures [2], to hypertension screening programs [3] and to health care programs for the elderly [4]. Inevitably, emergency medical services (EMS) will be evaluated not only on their effectiveness, but on their cost-effectiveness in comparison with other health programs.

Cost-effectiveness analysis is simple in concept: Collect the relevant costs, define an appropriate measure of effectiveness, and take the ratio of the two, arriving at the cost per unit of effectiveness. In practice, deciding what costs are "relevant" and which performance measures are "appropriate" is not so simple. There is a long list of possible costs and performance measures, and the choice depends on the perspective from which the analysis is being performed.

Although there is no simple "right way" out of this morass of costs and benefits, it is possible to develop some guidelines, and to flag some important issues that arise in applying cost effectiveness analysis to EMS. I will first discuss the range of purposes for which evaluations might be performed, and how these purposes affect the choice of costs and benefits. I will then discuss technical problems which arise when some specific measures of costs and benefits are employed, and the implications for cost-effectiveness analysis in emergency service systems.

Applying cost effectiveness analysis in the Emergency Medical System

Evaluations may be carried out for many reasons, and at a variety of levels within the system. This diversity of purposes and perspectives gives rise to the large number of cost and benefit measures which are proposed in EMS. We can quickly narrow the scope of appropriate costs and benefits for a particular simulation by asking: What is its purpose? The answer to this question will help determine the relevant cost and appropriate benefits by defining the boundary of the system to be examined.

What is the purpose of the evaluation?

Most evaluations fall into one of four types:

I. Licensure or accreditation evaluation.
II. Cross-site comparisons of EMS systems.
III. Evaluation of components of the EMS system.
IV. Comparison of EMS to other types of medical expenditures.

Licensure or accreditation evaluations are usually intended to eliminate extremely poor programs and to guarantee that no program falls below a minimum quality "floor." Although this is the most common type of evaluation carried out in EMS, it is the least informative. Almost all programs meet licensure standards, and no indication of relative quality among these licensed programs is attempted. Costs are rarely considered in these evaluations.

Comparing entire EMS systems across sites is often seen as a way to compare the relative costs of different organizational schemes, such as regionalization, central dispatching or different forms of ambulance ownership and control [5]. The goal of this kind of evaluation is to identify the "best" (that is, cheapest, or most efficient) way to organize a fixed set of resources. In this case, focusing on a measure of performance such as response time implicitly carries the assumption that faster response time will result in medical benefits which are never worse than those resulting from slower times. If the different organizational schemes incur roughly the same costs, then this use of operational performance measures can be useful in identifying the "best" organizational scheme. If the costs of the schemes are very different, however, and if the more expensive scheme is better (i.e., faster), then the assumption that faster responses give rise to better medical results must be examined and documented.

Evaluations of the third type-examining components of the EMS system—give rise to different problems. We most commonly think of the ambulance system and the emergency department as the core of the EMS system, but there are other components: Seattle has developed a pre-ambulance system consisting of volunteer lay responders who are trained in first aid and CPR [6]; physicians in their offices and in clinics often handle emergency complaints; and many emergency department visits end in hospitalization. EMS evaluations have focused on many different combinations of these components, and sometimes on parts of one component. The ambulance system in some communities is tiered, with basic emergency ambulances responding to most routine calls and a few mobile intensive care units (MICU's) responding to more serious cases. These mobile intensive care units are often subject to evaluation in isolation from the rest of the system [7-9].

The main problem, whether comparisons are being made across sites or within one site, is consistently defining the boundary of the subsystem being evaluated, so that the end result is not an apples-and-oranges comparison. If people in two communities use the EMS system differently, an evaluation of the same subsystem (e.g., the ambulance system) will involve a different patient population and thus no meaningful comparison is possible.

Schuman, Wolfe and Sepulveda studied twenty-six districts in a single rural county in Western Pennsylvania, looking at the need for ambulance service (evaluated from emergency department records) and the demand for ambulance service (measured by actual runs). The ratio of estimated demand to need in the twenty-six districts varied from .11 to .97. In the ten districts with the largest estimated need, the ratio varied from .11 to .44 [10]. With such different utilization patterns, any effort to evaluate the ambulance subsystem would have to include patients who provided their own transportation to achieve true comparability.

The bias introduced by this kind of selective usage is very important, even when the purpose of the evaluation is to compare the performance of two different ambulance classes (basic vehicles versus MICU's) within a single system. Intuition suggests that the most severely injured or critically ill patients are most likely to use the most sophisticated kind of transportation. We might expect ambulance-borne patients to have poorer outcomes than those who provide their own transportation, and MICU patients to have poorer outcomes than basic ambulance patients. However, when Hampton looked at this bias in comparing basic ambulance coronary patients to MICU coronary patients, he found that the *lower risk* patients were selected for the MICU's [11]. In Hampton's study, when this bias was ignored, the MICU's appeared to have better results than the ordinary ambulances; when the bias was controlled, the mortality rates in both types of vehicles were identical.

The fourth type of evaluation is rarely done at present, but the demand for comparisons of the relative value of different kinds of medical interventions is increasing. Health services researchers are developing the tools that will make this kind of comparison possible, and the threat of a cap on national health expenditures may require planners and policy makers to apply these tools or other methods to allocate scarce health resources. In this kind of evaluation, the benefit measures used must transcend the EMS system, so that various means of postponing death or reducing morbidity may be compared. This leads to such global benefit measures as "changes in life expectancy" or "change in heart disease mortality," and to costs evaluated from a global perspective, as well.

What is an appropriate measure of benefit?

There are two considerations here: First, will a particular performance measure be meaningful in theory? Second, will it be possible in practice to obtain the necessary data on a theoretically valid performance measure?

In 1974, Willemain [12] reviewed the many alternatives available in measuring the performance of emergency medical services. He considered three types of measures: input, process and outcome. Input measures are most often expressed in terms of resources per capita (for example, ambulances per 100,000 population or full-time emergency physicians per 100,000 population). Process measures focus on such characteristics as delays in obtaining emergency care, and "appropriateness" of service. Outcome measures include "lives saved" and changes in mortality or morbidity rates. Table 1 lists some of the measures that have been used or at least seriously proposed in the literature on EMS evaluation. The input measures listed in Table 1 are relatively easy to obtain, but fail the first test. That is, even after we obtain these measures, we do not know which of two systems is better. Do more ambulances per capita imply a better served population or an underutilized ambulance system? Input measures are most useful in establishing a quality floor below which no system should drop, and are the basis for most licensure or accreditation evaluations. (Even here rigid adherence to input standards may stifle innovations which deliver adequate emergency care substituting novel inputs for those specified in the

Table 1.

Input measures
Ambulances per capita Emergency physicians per capita Emergency departments per capita Runs per vehicle Runs per capita Emergency department visits per capita
Process measures
Ambulance response time Ambulance dispatch delay Appropriateness of transportation (e.g., MCCU, basic ambulance, own transportation) Appropriateness of emergency facility (e.g., burn center, trauma center, cardiac center) Resuscitation rate
Outcome measures
Lives saved Pre-hospital mortality Mortality at discharge from hospital X-day mortality (x = 180, 30, etc.) Life expectancy Community-wide CHD mortality

standards.) They are of little use in other types of evaluation since the availability of required inputs in no way guarantees that these inputs are being appropriately used to deliver appropriate emergency medical care.

Process measures include speed of response and the level of medical care. These may be used in licensure evaluations to establish floors similar to those generated with input measures. The EMSS Act of 1973 suggests a "speed of response" standard when it sets limits for response times in urban and rural settings. The "speed of response" measures are most appropriate when the purpose of an evaluation is to compare two (or more) ways to deliver the same kind of medical treatment. Then, if one system can deliver more of the treatment, or deliver it faster, it may be appropriate to assume that it is the better system. For example, response time is an adequate performance measure for distinguishing among different dispatching systems UNLESS the systems also provide different kinds of prehospital care or route responding vehicles to different classes of emergency department. If the medical treatments available at the destinations are different, then the system with the fastest response time is no longer necessarily the best. In this case, it may be sufficient to add a second "level of care" process measure. If both "speed of response" and "level of care" are better in a system, then it may be regarded as the better system. However, it is quite possible to find systems which are better on one measure and worse on another. In this case, process measures by themselves are no longer adequate. One must look further to the outcomes of care, either through the collection of outcome data or through the use of models which will convert process measures into expected outcomes.

Outcome measures will be necessary for type four evaluations or whenever a system change improves one aspect of the process of care, while degrading another. Not all outcome measures are created equal. "Lives saved," for example, is by itself a poor outcome measure. Since everyone dies eventually, deaths are not prevented, only postponed and the obvious question is for how long is death postponed? Prehospital mortality also gives an incomplete picture. For example, a decrease in prehospital mortality may be simply a reflection of faster response. Patients may be dying at exactly the same rate, and at exactly the same time following an emergency, but the system is now delivering patients to hospitals faster, so that those who once died in transit or at the scene now die in the emergency department. Mortality at one day or one month may be more meaningful, although long-term survival is still important. The Seattle emergency system has reported a substantial number of cardiac arrest "repeaters"—patients successfully resuscitated who arrest again in six months or a year. [13]

Efforts to use outcome measures in data-based evaluations run up against a very real problem of sample size. This is especially true for global or ultimate outcomes, as opposed to subsystem or intermediate outcomes. In general, health outcomes are influenced by a number of factors besides medical care—patient characteristics such as age, comorbidity and the severity of the disease, for example. As a result, variation in outcomes from one community to another or from one set of patients to another may be explained by differences in case mix, rather than by differences in medical care. This makes it difficult to convincingly attribute small changes in outcome to changes in the EMS system. There are three ways around this problem. The first is to use sufficiently large samples to obtain significant results despite the inherently large variation in outcome. The second is to adjust outcomes for case mix using various statistical models. The third is to use causal models to predict the changes in outcome measures from measures of process and intermediate outcomes.

For case-specific outcomes, it is often possible to obtain adequate sample sizes. For example, a change in the case fatality rate for ventricular fibrillation (VF) from 50 deaths per hundred cases to 35 deaths per hundred cases could be demonstrated with 136 cases of ventricular fibrillation.

Since VF is relatively rare, however, one would need to observe a million people for one year to obtain the necessary cases [14]. More global outcomes require more intensive data collection efforts. The above change in VF case fatality rate would result in at most 20 fewer deaths per year in a community of one million. This would translate into a change in the coronary heart disease mortality from 2 per thousand population to 1.98 per thousand population. Thus, if one were only monitoring the community-wide CHD mortality, one would need to observe over 30 million people for a year to have the same chance of demonstrating a significant change*. In this case, the experiences of those individuals who actually fibrillate are diluted by the experiences of those who die from other types of CHD at presumably unaltered rates.

The sample size calculations just described assume that no other changes in the environment or in medical treatment are occurring which might alter the rates being observed. In fact, it is impossible to control other factors, such as changes in lifestyle or diet, which may also be affecting a community's overall mortality. In the U.S., there has been a significant decline in heart disease mortality since 1968 [16]. There are many possible explanations for this decline—changes in the nation's lifestyle, improved emergency services, improved hospital services. Before proponents of any particular change can take credit for the decline, they will need to demonstrate a significant effect *after* controlling for other possible causes.

The second method of approaching outcomes is to employ statistical techniques which will reduce the unexplained variance in the outcomes being observed and thus reduce the effective sample size. Patients may be stratified into prognostic categories based on past experience. Another approach is to use a logistic model to estimate the expected outcomes based on variables which should influence outcomes. This is very similar to using prognostic strata, although it is possible to take into account a larger number of explanatory factors using the logistic model [14].

For outcomes such as changes in life expectancy, however, standard statistical models are not applicable. Neither is it practicable to collect the necessary data to estimate life expectancy from observed data. In this case, a mathematical modeling approach may be appropriate. It is possible to estimate changes in age-specific mortality rates that may be attributed to changes in process parameters or case specific mortalities. These rates can be combined in a life table calculation to estimate the changes in life expectancy for a hypothetical age cohort. [17] This cohort is an appropriate device for comparing diverse medical treatments such as preventive measures and interventions. However, the cohort is *only* a device, and it is folly to suppose that one could conduct a grand "cohort trial" of prevention versus intervention. There are technical difficulties in collecting data on any size cohort for several years, and in this case the sample size needed multiplies those problems. The model predicts that introducing a mobile coronary care unit might change life expectancy by about 0.12 years (out of approximately 70 years). Since the standard deviation of an individual's life expectancy from age 40 on is about 10 years [18], one would need to follow a cohort of 50,000 from age 40 to death to demonstrate a statistically significant change. (The massive Framingham Study started with about one tenth that number of people [19].)

What are the relevant costs?

Problems arise in assessing costs because of the many sources of financing that apply to most EMS systems. First there are the direct costs of running a system, including such items as salaries, equipment costs, repair and upkeep, supplies. However, many of these items may be contributed. For example, in a volunteer ambulance service the drivers and attendants are not paid. In addition, some equipment or services may be jointly shared with another organization. For example, a single dispatcher may dispatch ambulances and fire department vehicles. Finally, there are displaced or indirect costs. These occur when actions in the emergency medical system generate costs elsewhere, e.g., in the inpatient side of the hospital. Especially when a comparison involves two or more sites, there are several accounting issues which become important. Obviously, capital expenditures should be properly and comparably amortized. In addition, these three questions must be addressed.

i: How are contributed services valued?
ii: How are shared services valued?
iii: Should displaced costs of medical care be included?

The answer to the first question will depend on the perspective from which the evaluation is being performed. From a societal point of view, all contributed services must be counted at their face value. From the point of view of a city council voting next year's budget, however, the value of contributed services can be safely ignored. The second question is one which has plagued economists for some time: How do we handle activities or equipment which jointly contribute to the production of several goods or services at once? Consider a community in which a single dispatcher dispatches all ambulance and all fire department vehicles. There are three possible accounting procedures. First, all dispatching costs may be attributed to one department (fire or ambulance), in which case the other department is receiving dispatching as a contributed service. Second, the two departments may split the cost of dispatching based on the relative frequency of ambulance and fire dispatches. Third, the department which first developed the dispatching capability may charge the second department for *additional* salaries and equipment needed when the second dispatching function was added. The historical accident of which department came first will determine who bears the brunt of fixed costs, rather than relative utilization.

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* Using a significance level of 5 percent and power of 80 percent, the sample size n needed to show at change of magnitude x from a rate of magnitude p is given by the formula [15]: $n = [(p + x/2)(1 - p - x/2)6.2]/x^2$.

While the use of shared services may indeed lower costs, improper (or inconsistent) accounting may artificially lower costs in a system with many shared services. Table 2 compares some costs figures for the Boston and San Francisco ambulance services in 1968. The apparent ten-fold difference in costs may be partially explained by the fact that many ambulance runs in Boston were made by the police department, using police wagons, while in San Francisco this was not the practice.

How to deal with displaced medical costs is most critical when one evaluates from a societal point of view. An important consequence of lowering prehospital mortality (whether or not patients actually live longer) is that more patients arrive alive at the emergency department and must be treated there. When a mobile coronary care system successfully resuscitates twenty patients a year, those patients are then admitted to the hospital emergency department. If they live long enough, they are then admitted to a coronary care unit. In short, whatever changes in life expectancy are achieved by such resuscitative efforts, the price tag includes not just ambulance system costs but also some substantial hospital costs. If the survivors are in any way disabled (as many apparently are [20]), then substantial additional medical costs will be incurred throughout their life. A city council funding an ambulance system may have no interest in these displaced costs, but a society deciding to implement mobile coronary care on a widespread basis should be very interested in these cost ramifications.

Table 3: Direct and displaced costs of providing mobile coronary care service to a cohort of 10,000 males

	Per person	*Per year of life saved*
Direct costs	$14.20	$1,578
Displaced medical costs	$24.60	$2,732
Total	$38.80	$4,310

Discount rate of 5% was used in all calculations.

Source: Cretin [17]

These costs are not available from EMS records, but we can estimate them using models of the life history of a disease and patient interactions with the EMS system. For patients with myocardial infarction (and these patients appear to be less prone to recurrence than those with ventricular fibrilation in the absence of MI), such a model predicts that the displaced costs are about one and a half times as large as the direct costs (see Table 3). [17]

The use of this kind of model including displaced medical costs and lifetime benefits in a cost-effectiveness analysis raised another economic issue: What discount rate should be used in adjusting for costs and benefits which will occur far in the future? The figures quoted in Table 3 were obtained using a five percent discount rate on both costs and benefits. Even when the discount rate is changed to ten percent, or when no discounting is used, the relative size of displaced costs is 1½ to 2 times the direct costs.

Conclusions

Measuring costs and benefits in emergency medical systems is complex business. Global benefit measures require sample sizes that are beyond reach. Measures that are specific to a subgroup of patients or apply to only part of the system are subject to bias. If the evaluation is being per-

Table 2: Comparison of Boston and San Francisco ambulance services

	Population	*Number of ambulances*	*Ambulance runs per 1,000 population*	*Annual cost of service*	*Cost per run*	*Annual cost per ambulance*	*Annual cost per resident*
San Francisco	952,000	16	18	$1.1 million	$65	$69,000	$1.20
Boston	618,000	40	60	$0.25 million	$7	$6,300	$0.40

Source: Stevenson [21]

formed from a societal perspective, displaced costs—nearly impossible to measure directly—may be more important than direct costs. To those who find themselves involved in cost-effectiveness studies in EMS, I offer the following guidelines. First, in choosing a measure of benefit, use the simplest, most specific measure consistent with the objectives of the evaluation. Second, control for as many extraneous factors as possible. This does not mean to carry out randomized trials—randomization is no guarantee of homogeneity in small studies in any case—but it does imply that multivariate statistical techniques are preferable to t-tests. The data needed for logistic type analyses may be found in ongoing efforts to develop appropriate patient classification schemes [22]. Third, when using measures on subpopulations or on subsystems which are subject to bias, keep tabs on other variables which will reveal the magnitude and direction of possible biases. Fourth, when global measures of benefit and cost are indicated, employ a judicious combination of data-based estimates and model-based estimates.

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Epidemiologic studies in EMS systems*

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The essence of epidemiology is the extension of observations beyond the clinic or the hospital to the settings in which illnesses occur. The tendency in contemporary medical care is to concentrate measurements and observations on patients in health care facilities, away from their usual surroundings. As pointed out by Paul (1) in his work on clinical epidemiology, this also isolates the physician from the patients' surroundings and limits the realm of his investigations. Paul tells the classic story of Zenker's progress from the demonstration of trichinae at postmortem examination of the muscle tissue of a young woman, to the epidemiologic discovery of a link with the consumption of undercooked pork from pigs infested with the parasite. It was the return to and the investigation of "the scene of the crime" that was crucial.

How does this relate to the study of emergency medical services (EMS)? For one thing, EMS has the characteristic of reaching out, at least in part, to the site of the event, offering opportunities to investigate the circumstances surrounding the occurrence of the events that lead to activation of the EMS system. However, EMS is by definition a system designed to respond to a great variety of unscheduled events and, therefore, it does not immediately lend itself to the investigation of single, defined disease entities. Being a highly visible service, with an inherent quality of drama, the success of the process of providing service tends to be so highly valued that it overshadows and even discourages measures of the health outcome and impact of investments in EMS.

An epidemiologic approach to EMS can be undertaken in a number of ways, given a very broad definition of epidemiology, namely, the study of the distribution and determinants of various conditions of disease in a population. This allows the design of studies to describe who enters the system, how they enter, with what presenting conditions, when and whence, and possibly why this avenue of health care is chosen. In this manner, the EMS system becomes a community surveillance resource. Defined emergency events can be spotted by person, place, mode of entry, actions taken and flow through the system, and measurable outcomes. High-risk groups and potentially preventable conditions can be identified and insights gained regarding possible inadequacies in overall health care that lead persons to seek help through the EMS system. All of these approaches are apparent and, to some extent, they are being implemented. What appears to be lacking is a coordinated design for gathering such data to allow comparison across communities and over time as a basis for the development and evaluation of intervention strategies to achieve desired health outcomes.

One of the difficulties facing the epidemiologist is the demand for a global evaluation of EMS systems. This is, to a considerable extent, equivalent to the task of evaluating the overall health system in terms of its effects on the health status of the community. There are too many variables, too many confounding factors, and little possibility for the definition to appropriate controls. In fact, EMS evaluation is even more difficult than evaluation of the overall health care system, since its boundaries within the system are not very distinct and EMS is clearly affected by changes in other health care components.

What then is the realm of the epidemiologist in EMS research? First, the epidemiologist offers an approach to defining the population at risk. This goes far beyond the set of patients seen in any component of the EMS system. For example, if the focus of a study is the total EMS user population, the epidemiologist would seek to conduct a general population survey to identify the differences between the users and the non-users, so that predictions may be made of the likelihood of system utilization by defined population subgroups. Such information also offers an opportunity to formulate and test hypotheses regarding the reasons for use or non-use of the system and to design and test strategies for altering use patterns. By adding valid measurements of outcome, the health effects of any change may be assessed.

The difficulties encountered in such evaluations are well presented by Borgatta (2) in his discussion

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of research problems in the evaluation of health service demonstrations. The experience in EMS studies has been, in general, that system evaluations are very difficult to conduct in a rigorous manner and that generalizability is very limited. Consequently, I should like to dwell on a number of studies, broadly epidemiological in nature, that may lend some clarification of the potential for such research in EMS.

Emergency Care of Acute Myocardial Infarctions

During the past decade the concept of the mobile intensive care unit or mobile coronary care unit (MCCU) has gained wide acceptance. At this time, we shall not attempt a review of the somewhat confusing literature, but there is some evidence that lives are being saved by the MCCU's. However, there remain many unanswered questions regarding the characteristics of the users of such services and the overall impact of this EMS component in lowering potential mortality. We undertook a study of the MCCU in Columbus, where this is a well established service, inaugurated 8 years ago. The vehicles can reach any part of the city in less than 7 minutes, and under normal conditions the majority of cases are under the care of paramedics within 5 minutes.

In order to characterize users and non-users we have secured a sample of patients treated by the MCCU and a control sample of patients admitted with a diagnosis of presumptive acute myocardial infarction (AMI), in the same set of hospitals. Each case was reviewed by cardiologists to verify the diagnosis of AMI and to evaluate the performance of the paramedics in the MCCU cases. Users and non-users were matched by age and sex.

Interviews with MCCU cases and controls revealed that 57 percent had prodromal symptoms, with median duration of 14 days, and that 34 percent consulted physicians during the prodromal period (3). The most common prodromata were chest pain, sudden fatigue, and dyspnea. Females reported prodromata significantly more frequently than males; patients with prior coronary heart disease reported the presence of symptoms more frequently than those with no such history. Patients who utilized the MCCU reported prodromata more frequently, and were more likely to interpret the symptoms as heart-related, than non-users. The median duration of prodromata was also longer among the MCCU users. It is interesting to note that the time lapse from the onset of acute symptoms to the activation of the system, i.e., call for MCCU or departure for hospital emergency department, tended to be longer in the cases in which prodromal symptoms were reported.

This preliminary analysis suggests that the decision to use the MCCU is conditioned by the presence of prodromal symptoms and by medical care received prior to the acute symptom onset. The study will also allow the comparison of the occurrence and nature of the prodromata and the use of the MCCU among patients who are confirmed as having AMI with those with suspected AMI who are found to have other conditions.

In an early analysis of 148 users and 131 non-users with AMI, considerable difference was found in the median time from onset to declaration of an emergency, i.e., call for MCCU or departure for hospital emergency department by other means. MCCU users had a median time of 45 minutes, as compared with 252 minutes for non-users. In attempting to assess the severity of illness in both groups, it was found that the percentage of transmural myocardial infractions was about the same, but the other indicators showed greater severity in the MCCU users. For example, the peak enzyme levels, an index of the extent of myocardial damage, was significantly greater in the MCCU users and they had a much greater incidence of complications (e.g., pulmonary edema, shock, severe bradycardia, cardiac arrest). What was most revealing was the extremely low incidence of hospital mortality among the patients that arrived by means other than the MCCU. In the first 131 non-MCCU patients, there was only 1.5 percent mortality. At the same time, the hospital mortality of 148 AMI patients treated and transported by the MCCU was 19.1 percent. It is evident that MCCU treatment is generally received by the most severe cases, who have the greatest risk of mortality. Another factor is the high level of utilization of the Columbus EMS system, in which approximately half of all AMI's, including sudden deaths, are treated by the system in the pre-hospital phase. These findings will be more thoroughly investigated in the analysis of 1104 cases that comprise the total study sample. However, we may already be seeing evidence of a level of diminishing returns in the reduction of mortality from AMI through the use of MCCU in a system that is well established and well used (4).

It is interesting to note that the paramedics, in this system, provide care according to a set of specific protocols developed by an advisory panel of physicians authorized by city ordinance to guide the system. The paramedics read ECG's and carry out cardiopulmonary resuscitation, intubation, administration of drugs and intravenous fluids, and apply defibrillation substituting protocols for telemetry or voice communication with physician consultants.

It appears that patients with the less severe, uncomplicated AMI's tend not to use the MCCU, despite the fact that 96 percent are aware of its availability. In the MCCU cases, cardiologist review indicated that the paramedics interpreted the ECG's correctly in 93 percent of the cases and followed the treatment protocol effectively in 94 percent.

The 148 MCCU cases included 22 who showed initial ventricular fibrillation and 12 of those (55 percent), were long-time survivors.

The collection of the data for this study is now approaching completion. In general, we are finding that about half the cases that enter the system, by either mode, are confirmed as having AMI. The data include a sample of recordings of the messages that originally led to the dispatch of the MCCU; interviews with all MCCU cases and controls; the reports filed by the MCCU's including the ECG strips; abstracts of the hospital records including all lab data and complications; cardiologists' review of the MCCU reports and hospital record abstracts; and six-month follow-up of all patients discharged from the hospital alive. In addition, the PAS reports of all area hospitals are obtained in order to establish a denominator of the total number of cases discharged with a diagnosis of AMI. These data, which include age, sex, length of stay, and condition on discharge, will allow extrapolation to the population at risk in the area of study.

We have run into an interesting variable in the 6-month follow-up. With increasing frequency, patients recovering from AMI are undergoing coronary by-pass surgery. It is still too soon to assess the magnitude of this factor and we do not as yet know how to deal with this as an additional predictor of survival. There are complex criteria in case selection for surgery and these differ from one surgical team to another. At least, we will be able to indicate an approach to dealing with the effects of such post-emergency medical interventions as variables in the study of long-term morbidity and mortality after entry into the EMS system.

Table 1 presents estimates of lives saved by EMS in Columbus in relation to the total incidence of AMI. The estimates were based on our experience in the study of sudden death (5, 6, 7), on data collected by the EMS system since the initiation of the Heartmobile (MCCU) in 1969 (8), and on estimates of incidence from various national studies. In Table 1, estimates of percent saved (i.e., discharged alive from hospital) are made for first AMI and subsequent AMI's, as well as for "sudden deaths" and other AMI's. The greatest percent saved by MCCU is, naturally, in the cases of potential sudden death. The overall decrement in expected mortality was estimated at 7.4 percent.

Figure 1 presents the size of various subgroups, with estimates made on the basis of the above data sources and the early findings of the present MCCU study. In this figure the first and subsequent AMI's are combined, but the estimates of

Table 1: Estimates of EMS salvage in AMI mortality in Columbus, Ohio (2500/yr or 3ˉ/1000/yr.)

	Sudden death	Other AMI	Total
1st AMT	500	1000	1500
Saved* by EMS	70 (.140)	45 (.045)	115 (.076)
2nd AMT	400	600	1000
Saved by EMS	40 (.100)	30 (.050)	70 (.070)
Total	900	1600	2500
Saved by EMS	110 (.122)	75 (.047)	185 (.074)

*Discharged from hospital alive.

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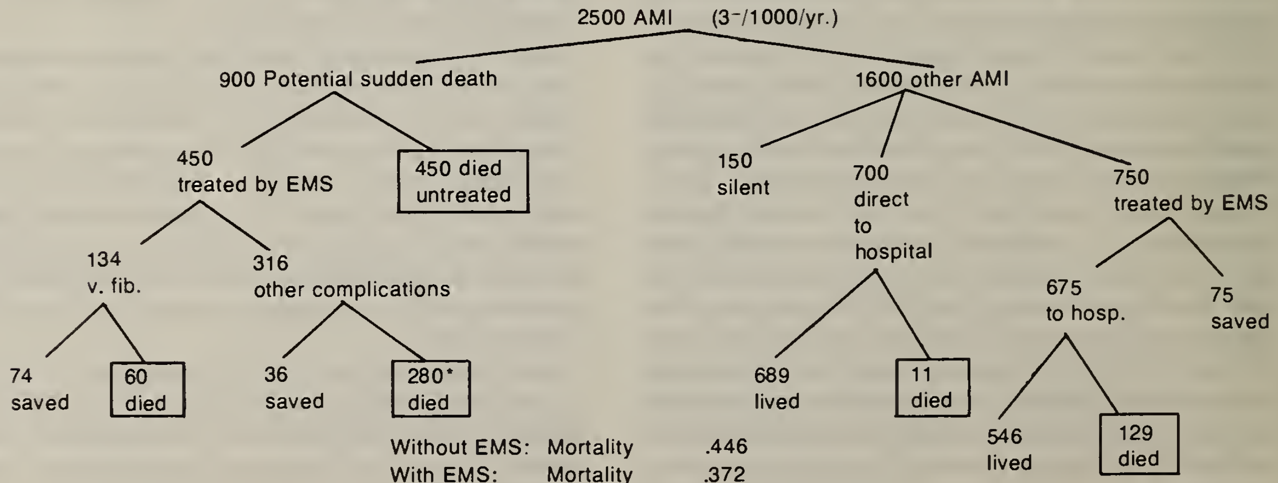
Figure 1: Estimates for Columbus, Ohio



Without EMS:	Mortality	.446
With EMS:	Mortality	.372
Difference:	Mortality	.074

*Including DOA, no heart function re-established.

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potential sudden deaths and other AMI's are presented separately. There is an estimated reduction from an expected mortality of .446 to .372, or a difference of 7.4 percent attributable to MCCU intervention. This presupposes that approximately half of the recognizable AMI's, including the sudden deaths, are treated by the MCCU, and this appears to be the case in the Columbus EMS system.

Field studies

The traditional field study involves "shoe-leather" epidemiology, going out to "where it's happening" and gathering the data while they are still fresh. It became apparent to us from our studies of sudden death that, even in extreme cases, there was much delay and floundering before entering a call to the EMS system. It was decided that a study be conducted to find out how people behave in seeking help in cases for which EMS is eventually summoned (9). Arrangements were made for investigators to accompany the responding EMS vehicles to interview the people at the site of the emergency event regarding the pathways taken in seeking aid. In 265 EMS runs it was found that a significant proportion of callers went through complex channels with many calls and delays, even after it became apparent to them that emergency care was needed. Table 2 shows the frequency of complex pathways (multiple intervening communications) in emergencies that occurred at various sites. For example, 34 percent of the illnesses and 45 percent of the injuries that occurred in homes were associated with complex pathways of summoning EMS. In the cases of illness, 16 percent called physicians, while in no case of injury was a physician called. In auto accidents, the calls were directly to EMS or police. In places of work and indoor public places, calls were most frequently placed through an official. This might indicate the necessity of training appropriate people in industrial and commercial establishments, in schools, and in public places regarding the best ways to summon EMS and, perhaps, in what to do until help arrives. It was also interesting to note that in Columbus, where a well-established system exists and a seven-digit access number has been advertised for a long time, 93 percent of the calls were entered by dialing "0". (At present, although there is no 911 system in Columbus, dialing 911 reaches an operator who is instructed to transfer the call to the EMS dispatching center when the caller indicates a need for EMS.)

In the course of this study, it was found that the recorded messages entering the EMS dispatching center could serve as another avenue to gaining insight into emergency communications. A major study was undertaken to investigate the nature and effect of EMS messages (10). Figures 2 and 3 present the epidemiologic model in terms of the sequence of possible actions, the realm of the communication study, and the flow of data acquisition. This study required attendance by investigators at the EMS dispatching center, retrieval of reports of the responding EMT's, and follow-up of patients to receiving hospital emergency departments. The findings are too complex to be briefly presented in this paper, but it is clear that dispatching is significantly related to the identities of the caller and the victim and the site of the emergency event, as well as the nature of the emergency problem stated by the caller. Time of day, day of week, and busy

Table 2: EMS communication study, Columbus, Ohio 265 accompanied ambulance runs

Home/ill (.33)	#	%	*Home/trauma (.22)*	#	%
X→ OP/EMS	3	3	X→ OP/EMS	4	7
X→Y→ OP/EMS	30	34	X→Y→ OP/EMS	23	40
Complex	30	34	Complex	26	45
Found	11	13	Found	5	8
Call physician	14	16	Call physician	0	0
Total	88	100	Total	58	100
Auto accid (.15)	#	%	*Outdoor/other (.10)*	#	%
Bystander→Police	12	30	Bystander→ OP/EMS	9	35
" → OP/EMS	21	53	Complex	14	54
Via intermed→ police	3	7	X→Y→ OP/EMS	3	11
" → OP/EMS	4	10			
Total	40	100	Total	26	100
Public indoor (.11)	#	%	*Place of work (.09)*	#	%
Bystander→ OP/EMS	8	27	Co-worker→— OP/EMS	8	33
Via official	17	59	Via official	12	50
Complex	4	14	Complex	4	17
Total	29	100	Total	24	100

X = Patient
Y = Relative, friend, neighbor
OP/EMS = Dialed "O", or direct EMS number
Complex = Multiple intervening communications

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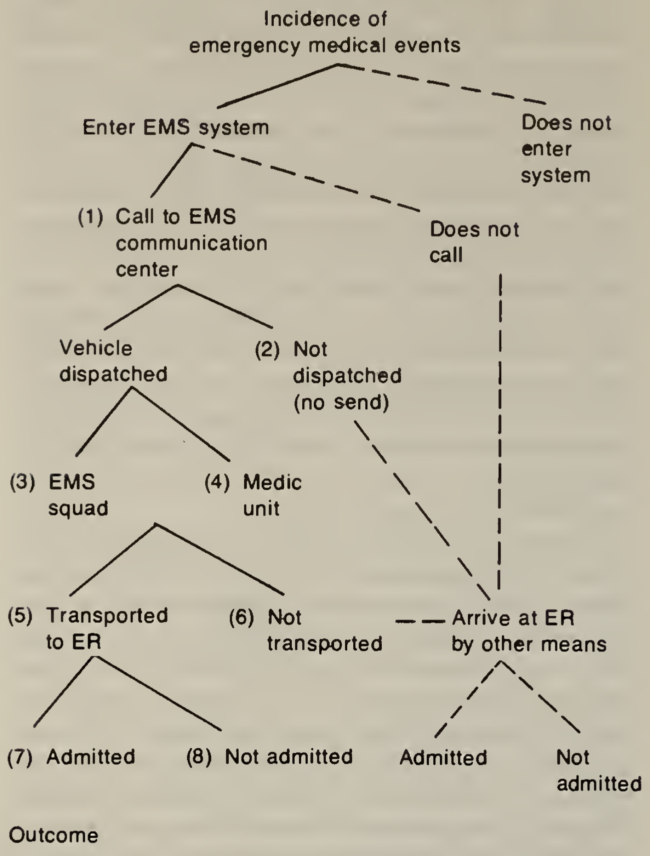
Figure 2: Sequence of possible actions



——— Data included in present study
— — — — — Data not included in present study

Source of Data:

(1) - Calls recorded and logged at the EMS Communication Center.
(2), (3), (4) - Dispatching decision in Communication Center log.
(5), (6) - Reports of EMS Squad/Medic Units.
(7), (8) - Follow-up of transported patients to obtain information from ER records.

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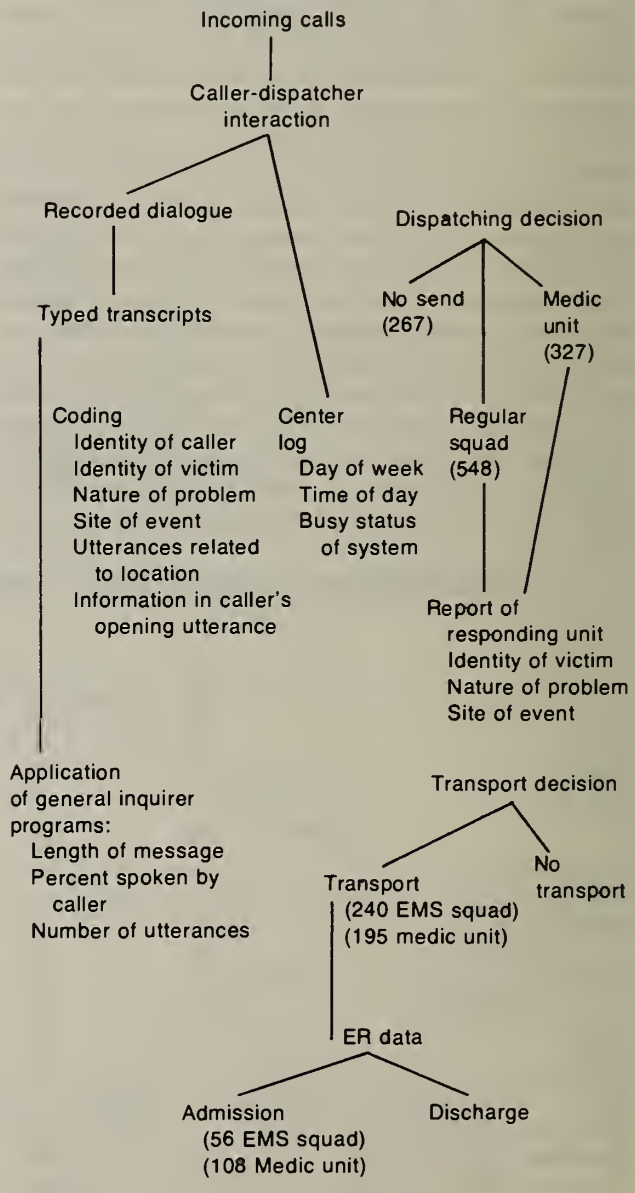
status of the system were also determining factors. It is apparent that communication triage is the hallmark of an effective system. Otherwise, without unlimited resources, the response is "first come, first served" and there is no way to assign priorities in a multi-tiered system that has both basic and advanced life-support units. A communication system requires knowledge of the factors that affect dispatching decision in order to develop effective communication triage policies.

An immediate application of this study was another study, in which a sample of recorded messages was played to panels of dispatchers and physicians, for their rating of the quality of the performance and their suggestions for communication algorithms (11). This study is now nearing completion. We have determined the areas of agreement and disagreement within and between the panels and have identified the cases they rated best and worst. From this we are seeking to construct a manual for the use of any EMS system in evaluating their communication processes and developing training programs specifically aimed at the needs of the EMS dispatchers in their communities. There are many other applications and extensions of the basic emergency message study that are being developed. These involve problems of consumer information and education, local linguistic variations that may affect communication, and general approaches to improving the communication process and facilitating triage and dispatching decision.

Population surveys and simulation models

A basic approach in epidemiologic studies is the population survey. In EMS studies this forces the system to look beyond its boundaries, to count the

Figure 3: Flow of data acquisition



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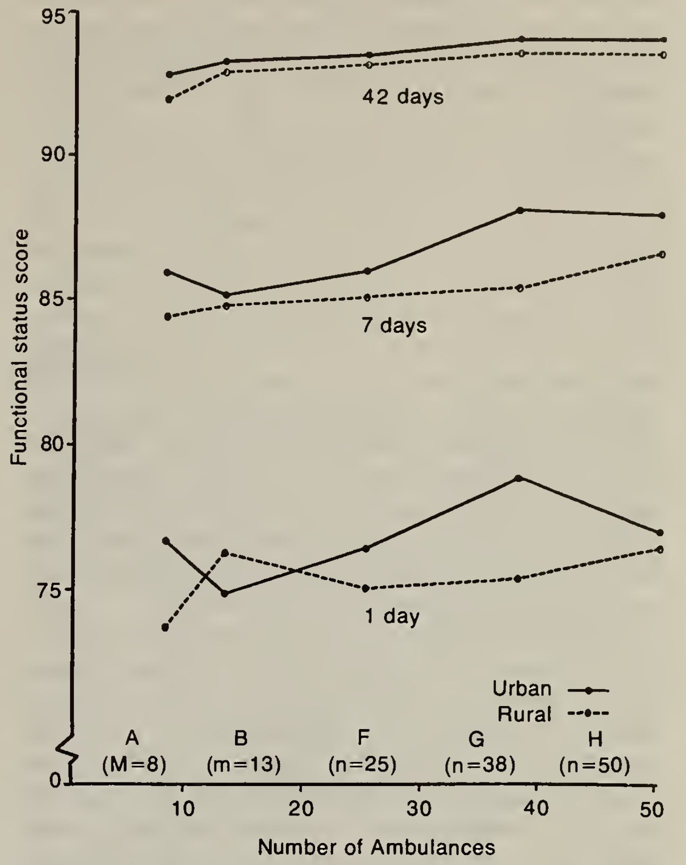
cases it missed as well as the population served. It is a truism that systems that study only those that enter are bound to appear over-used, for they tally the "false positives" but not the "false negative"—those who should have entered but did not. The detection of under-utilization requires reaching out beyond the system and into the population that needed service but did not receive it, the false negatives.

In the evaluation of an EMS demonstration project in Southeastern Ohio (12), a multi-stage, stratified, cluster sampling method was used to obtain a representative sample of the households in a seven county demonstration area. This method afforded the economy of cluster sampling as opposed to simple random sampling that would have required extensive travel throughout the large study area. This method also introduced the complexities of design effect, but it kept the cost of the study within reasonable bounds. The survey was conducted twice, early in the course of the demonstration and again 15 months later, when the system had achieved widespread recognition and full operation. The data revealed the social and demographic characteristics of users and non-users, their knowledge of the system and their attitudes toward its services, and the instances in which the system may have been needed but was not used. The surveys allowed measurement of change over time and, for the epidemiologist, they offered a basis for generating hypotheses regarding the effects of change and the development of strategies of intervention to achieve desired goals.

The surveys were coupled with the collection of detailed information regarding the location of emergency events, the utilization of each subsystem (communications, emergency squads, hospital emergency departments), staffing, policies, operational procedures, and the general geography, road systems, and time and distance factors in the demonstration area. This information was entered into a model designed to simulate an EMS system (13). By utilizing the model, predictions could be made regarding the probable effects of change. For example, Figure 4 presents the effect of the number of ambulances serving the system on the functional status (health status) of patients receiving pre-hospital emergency care. To achieve this, expert opinion was required regarding the potential health effects of response time on outcome in a large variety of illnesses and injuries. A panel of emergency physicians was used to reach consensus estimates of such effects in 162 conditions that were most commonly seen in the system. It appeared that they considered response time, within relevant bounds, to be significant in only a small number of conditions. As can be seen in Figure 4, there is a small increase in predicted functional status with increase in number of ambulances. At 42 days after an emergency event, the differences are small enough to raise some question regarding the excess cost of increasing the number of ambulances beyond simulation B (13 ambulances). However, these estimates depend on the validity of the health outcome predictions made by the expert panel. The epidemiologist would insist on validating these predictions by detailed follow-up of a representative sample of cases to determine actual functional status at specified times.

Figure 4: Functional status scores for patients in urban and rural areas transported by SEQUEMS ambulances for five simulations and three followup periods



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The future of epidemiology in EMS research

We have spoken primarily of work done in a department that is oriented to epidemiologic research and, consequently, sees much of what it does in these terms. Others may carry out similar studies and label them differently. However, the epidemiologic view impels the investigator along roads that may not otherwise be taken.

Who enters the system and what population denominators do they represent? Who is missed by the system and what groups do they represent? Why the differences? What are the effects of time and place? Are there "epidemics" of emergency events? What are the secular trends in the incidence of specified "emergencies"? Are there endemic rates that can be determined as baselines of expected incidence in each EMS system? These are the key questions.

As we develop economical methods for gathering the data required to answer these questions, we can proceed to measure effects of "natural" events in the community, of changes in population, of changes in the EMS system, and of intervention programs aimed at the prevention or control of specific diseases that impinge on the EMS systems.

An important area of epidemiology that has been little used in EMS is the establishment of the EMS system as a resource for health surveillance in a given region or, through compatible data systems, on state and national levels. To some extent this was attempted in the product-injury surveillance program, but the program lacked the necessary shoe-leather epidemiology follow-up to investigate potential problems adequately. Epidemiologic surveillance based in the EMS system is applicable to outbreaks of acute infectious disease, poisonings, drug overdose, child abuse, and a variety of other definable conditions that merit the continual vigilance of health authorities.

The EMS system is also a sensitive barometer of critical community problems in health care delivery. EMS must respond to patient demands and must also be ready to determine why these demands are being made of the EMS system. Are they appropriate to the EMS system? Are they the result of malfunctions in the overall health care system? In our view, these are epidemiologic questions, and the epidemiologists have just barely extended their interests to this field of research.

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The influence of uncertainty on decision making in EMS councils

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Abstract

Analytical decision models and *interactive* decision approaches are described in terms of decision making that might occur in an EMS council. The influence of uncertainty on these decision models is discussed. *Uncertainty* is defined as having temporal, procedural, quantifiability, and domain attributes. Highly uncertain decisions are unique, and have unknown decision procedures. Decision premises, like available funds or demands for services, are constantly shifting in uncertain environments. Low uncertainty occurs when decisions are repeatable and follow known procedures. Past practices can be used as templates when uncertaintly is "low" because funding levels and use rates are predictable. The results (e.g., validity, risk of omission, etc.) of applying interactive and analytical decision models under varying levels of uncertainty are discussed.

Note: This presentation, in revised form, has been accepted for publication by *Medical Care* under the title, "Some Considerations in Selecting Interactive Analytical Decision Approaches for EMS Councils."

Quality assurance in an emergency service: The computerized clinical algorithm*

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Introduction

The importance of developing a feasible and useful quality assurance system for emergency medical care has been recognized by both consumers and providers, but the most appropriate methodology to achieve this system has, to date remained elusive. Early efforts in the appraisal of medical care quality relied on peer review using *implicit* criteria, but suffered from subjectivity and lack of generalizability. This approach was replaced by the use of lists of *explicit* criteria, which achieved objectivity but at the expense of validity. The lists of criteria usually ignored the fact that different patients with the same diagnosis or problem often require different patterns of care. Such an oversimplification of the medical care process led to questionable conclusions about the quality of care. What is needed is an evaluative instrument which is objective, but which is also sufficiently sophisticated to monitor the highly complex activity of medical care on a case-by-case basis.

It is sometimes argued that clinical medicine is an "art" which cannot be described systematically or evaluated objectively because of its subtleties and complexities. According to this argument it would be impossible to construct a set of standards that is sufficiently sophisticated to monitor the practice of medicine.* In fact, a number of investigators have demonstrated that, while medicine is complex, it is not beyond analysis. They have developed clinical algorithms which describe the management of such common problems as upper respiratory infection, urinary tract infection, low back pain, and heart attack.[1-6] These algorithms provide a framework to present an explicity, detailed account of various processes of medical care and on an individual care basis. They are practical tools for evaluation because they are unambiguous, and are sophisticated and meaningful because they simulate a clinician's branching logic.

While a variety of clinical algorithms have been developed to describe the management of specific clinical problems, very few investigators have demonstrated how to use algorithms within a quality assurance system to monitor, evaluate, and improve patient care. Some work has been done with physician extenders, [3,6] and a few algorithm studies have evaluated physician care.[7] The present paper describes the use of a clinical algorithm as the basis for a computerized quality assurance system for a specific clinical problem (lacerations) in an emergency service (ES).

Methods and results

The following discussion considers (1) the development and testing of a clinical algorithm, (2) the acquisition of data for medical care audit, and (3) the evaluation of care using algorithmic criteria.

(1) Development and testing of a clinical algorithm. An algorithm contains explicit criteria for making decisions, as well as instructions for collecting historical and clinical data, for performing diagnostic tests, and for initiating therapies. The algorithm for laceration care (Fig. 1) was developed by the authors and a panel of plastic and reconstructive surgeons. In designing the algorithm, the clinicians translated their practical experience and knowledge of the literature into a set of explicit instructions and decision-making criteria that are internally consistent and unambiguous. The algorithm was then refined by tracing 50 representative cases through the logic

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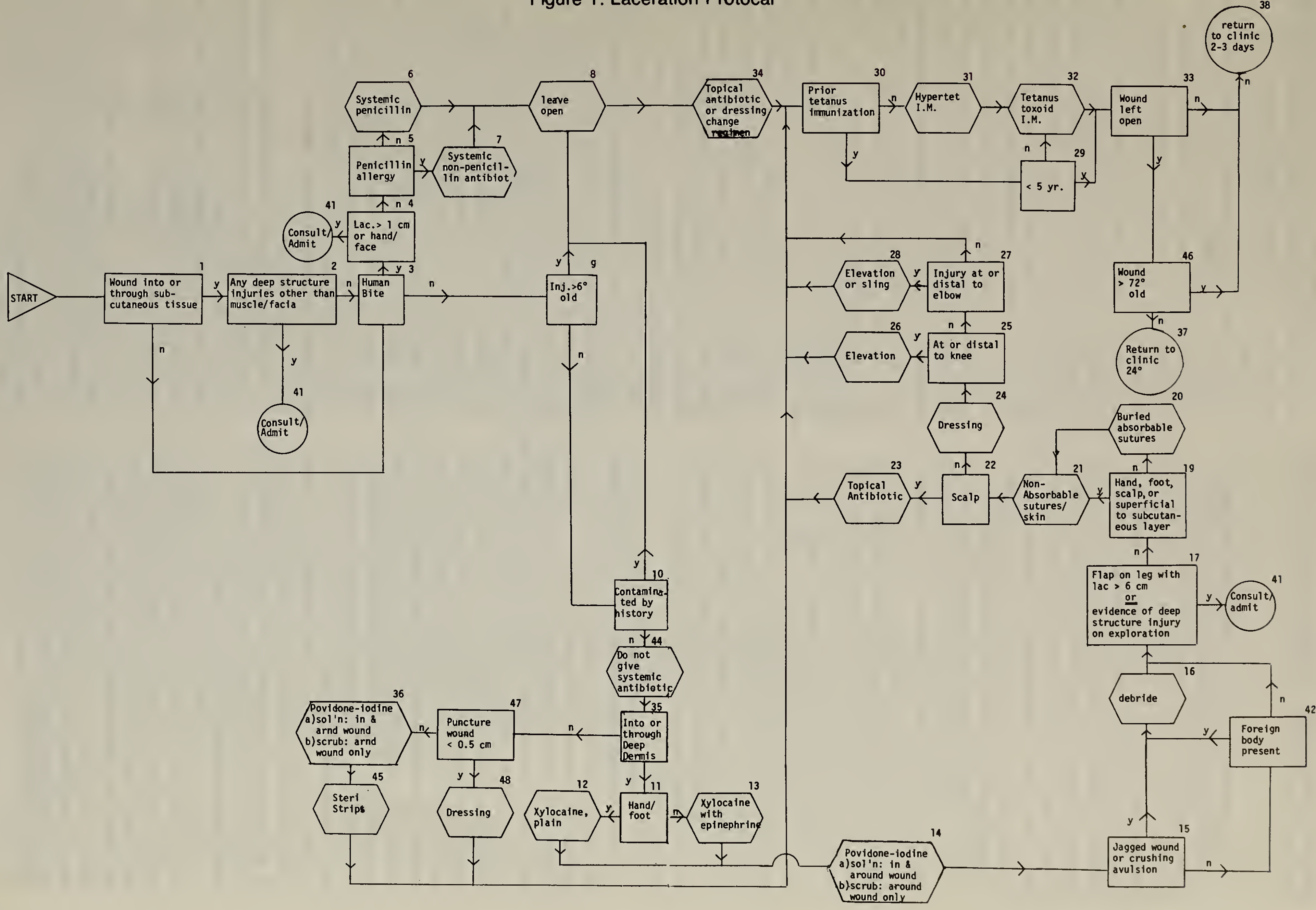
*This argument is, in part, responsible for the PSRO legislative terminology of "norms" (i.e. a *range* of acceptable activities) as opposed to a more strict set of criteria, and even complete reliance on established "norms" is discouraged by incorporation into the immunity clause language requiring the physician to exercise "due care." [8-12]

Figure 1: Laceration Protocal


START
1
Wound into or through sub-cutaneous tissue
y
n
2
Any deep structure injuries other than muscle/facia
y
41
Consult/ Admit
n
3
Human Bite
y
n
4
Lac.> 1 cm or hand/ face
y
41
Consult/ Admit
n
5
Penicillin allergy
n
y
6
Systemic penicillin
7
Systemic non-penicil-lin antibiot
8
leave open
g
Inj.>6° old
y
n
10
Contaminated by history
y
n
44
Do not give systemic antibiotic
35
Into or through Deep Dermis
n
y
47
Puncture wound < 0.5 cm
n
y
36
Povidone-iodine a)sol'n: in & arnd wound b)scrub: arnd wound only
45
Steri Strips
48
Dressing
11
Hand/ foot
y
n
12
Xylocaine, plain
13
Xylocaine with epinephrine
14
Povidone-iodine a)sol'n: in & around wound b)scrub: around wound only
15
Jagged wound or crushing avulsion
y
n
42
Foreign body present
y
n
16
debride
17
Flap on leg with lac > 6 cm or evidence of deep structure injury on exploration
y
41
Consult/ admit
n
19
Hand, foot, scalp, or superficial to subcutaneous layer
y
n
20
Buried absorbable sutures
21
Non-Absorbable sutures/ skin
22
Scalp
y
n
23
Topical Antibiotic
24
Dressing
25
At or distal to knee
y
n
26
Elevation
27
Injury at or distal to elbow
y
n
28
Elevation or sling
34
Topical antibiotic or dressing change regimen
30
Prior tetanus immunization
n
y
31
Hypertet I.M.
29
< 5 yr.
n
y
32
Tetanus toxoid I.M.
33
Wound left open
n
y
46
Wound > 72° old
y
n
37
Return to clinic 24°
38
return to clinic 2-3 days

pathways and making changes to improve completeness and clinical acceptability.

(2) Acquisition of data for medical care audit. A clinical algorithm is composed of a network of nodes, each of which contains either a decision-making criterion or an instruction to perform a specific task. In Figure 1, decision nodes are represented by rectangles, and performance nodes by hexagons. Each decision node branches into two alternative paths; the selection of the correct path depends upon whether or not the decision criterion is satisfied. Determining the correct path through the entire algorithm involves the successive application of a series of decision criteria.

Identifying the correct path requires knowledge of the variables upon which decisions are based. Unless these variables are known, the evaluator cannot determine whether the correct path was chosen, and consequently cannot know what treatments are indicated. If the evaluator does not know what treatments are indicated, he cannot determine whether the treatments actually given were appropriate. An adequate data set for evaluation must, therefore, include all of the variables contained in the series of nodes along a specific path through the algorithm. One can then evaluate performance of a provider by comparing the actual treatments with the recommendations of the algorithm.

The above discussion provides a basis for determining whether a given data source is adequate for quality assurance. A node is labeled “determinant” if the variables required by the node can be determined from available data. An ideal data source is one which provides, for each case, a path of nodes all of which are determinant. To make comparisons, the “adequacy” of a data source may be defined as a percentage consisting of the number of determinant nodes divided by the total number of nodes encountered. For example, if the appropriate path for a given patient contains 20 nodes and the available data provides information about 15 of them, then the data source in question has an adequacy of 75 percent for that case. A reasonable measure of the overall adequacy of a data source would be obtained by considering a series of patients and computing the total number of determinant nodes divided by the total number of nodes encountered by all of the patients.

In order to assess the adequacy of the standard ES medical record as a data source for medical audit, a series of laceration cases, during treatment, were observed by members of the research staff who recorded details of the care process on a special form (Fig 2). The observer’s record provided a complete description of the history, physical examination and treatment which could be compared with the description found in the medical record.

Approximately 20 percent of laceration cases treated during a five-month period were seen by an observer. The written medical records of these 576 patients were abstracted onto forms identical to those used by the observers. These cases were used to derive preliminary results concerning the adequacy of the handwritten medical record.

The cases were analyzed by subjecting them to a computerized node analysis. Each case was traced through the laceration algorithm, and the data pertaining to each node were examined. The analysis produced a “+”, “−”, or “s” for each node encountered. The +’s identify nodes at which the physician had recorded the pertinent information, and the −’s nodes where he had not. An “s” can only be recorded at a decision node. This symbol indicates that the physician had not merely neglected to *record* the necessary data but that he actually failed to *elicit* the data during the history or physical examination. Node 9 of the algorithm, for example, asks about time since injury. If the physician gathered this information from the patient, but failed to record it on the medical record, he receives a “−” at node 9. If he neglected to ask the patient for this information, however, node 9 receives an “s.” In that case, the variable “time since injury” is unknown, and the analysis cannot proceed because the subsequent path depends upon this variable. An “s,” therefore, indicates that the analysis of the case had to stop because of the unavailability of data.

Of the 8379 nodes encountered by the 576 patients, 6562 were determinant (“+”) and 1817 were indeterminant (“−”). This yields an overall coefficient of “adequacy” of 78% (6562/8379) for these medical records. These results indicate that for laceration cases the physician neglects to record approximately one-fifth of the data necessary for evaluation. The significance of this finding can be appreciated by realizing that a single indeterminate decision node would terminate the analysis of a case in the absence of the observer’s “backup” data. All but 22 of the 576 cases had at least one such node.** These results suggest that an ES quality assurance system cannot be based on the medical record in its current form, assuming that the results for laceration patients also hold true for other patient groups.

To determine if the “adequacy” of the medical record could be increased, the hand written medical record for laceration cases was replaced by a structured checklist similar to the one used by the observers (Figure 2). To measure improvement in the completeness of the record, a series of 99 cases

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*The average number of nodes encountered was 14.5 per patient (8379/576). The probability that a given node is indeterminant is 1817/8379 = .22. Therefore, the probability that a given medical record will contain no indeterminant nodes is $(1-.22)^{14.5} = .027$. Hence, among 576 records, one would expect to find (.027) (576) = 16 such records, compared to the observed 22.

Figure 2:

EMERGENCY SERVICE VISIT RECORD - ADDENDUM
YALE-NEW HAVEN HOSPITAL

OPEN SOFT TISSUE WOUNDS

(Complete form for most serious wound - use Remarks Section for additional data)

Name:

Birthdate:

Unit Number:

- VISIT DATE ____________
- TIME SINCE INJURY ____________
- MECHANISM OF INJURY ____________
____
- ESTIMATED BACTERIAL CONTAMINATION
  - 1 ☐ low (e.g. glass, knife) ⎤ $\leq 10^5$
  - 2 ☐ moderate (e.g. pavement, wood) ⎦
  - 3 ☐ high (e.g. barnyard, sewer) — $>10^5$
- PRIOR TETANUS IMMUNIZATION
  - 4 ☐ never or patient uncertain
  - Yes: 1 ☐ < 5 yrs.
    - 2 ☐ ≥ 5 yrs.
    - 3 ☐ pt. uncertain when last T.T.
  - 5 ☐ pt. not asked
- DRUG ALLERGIES
  - 1 ☐ none 3 ☐ other: ____________
  - 2 ☐ penicillin 4 ☐ not asked
- TYPE OF INJURY
  - 1 ☐ cutting laceration 5 ☐ amputation
  - 2 ☐ tearing laceration 6 ☐ puncture wound
  - 3 ☐ crushing laceration 7 ☐ abrasion
  - 4 ☐ avulsion 8 ☐ other: ________
- WOUND DEMENSIONS (estimated)
  - length ______ (cm) width ______ (cm)
- FLAPS & TISSUE LOSS
  - 1 ☐ none 5 ☐ multiple flaps
  - 2 ☐ proximal based 6 ☐ signif. tissue loss
  - 3 ☐ distal or lateral based
- DEEPEST TISSUE INVOLVED
  - 1 ☐ superf. dermis 4 ☐ fascia
  - 2 ☐ deep dermis 5 ☐ muscle
  - 3 ☐ subcutaneous 6 ☐ periosteum
- DEEP STRUCTURE INJURIES
  - 1 ☐ none 3 ☐ muscle
  - 2 ☐ fascia 4 ☐ other: ____________
  - Exam: ____________
____

- LOCATION & DESCRIPTION OF WOUND
____
____
____
____
- CONSULTS FOR WOUND
  - 1 ☐ no 2 ☐ yes: ____________
  - Reason: ☐ advice
    - ☐ transfer management
- ANESTHETIC
  - 1 ☐ xylocaine, plain 3 ☐ other: ________
  - 2 ☐ xylo. $\bar{c}$ epinephr 5 ☐ none
- SKIN PREP.

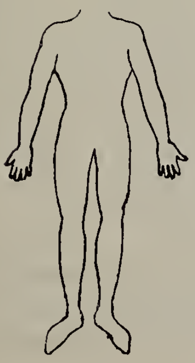
	in wound		around wound
antiseptic soln.	☐	1	☐
antiseptic scrub	☐	2	☐
other: ________	☐	4	☐
none ☐ 5			

- IRRIGATION
  - 1 ☐ no 2 ☐ yes: ____________
- FOREIGN BODIES
  - 1 ☐ no 2 ☐ yes: ____________
- DEBRIDEMENT
  - 1 ☐ no 2 ☐ yes: Layers ____________
    - Reason ____________
- WOUND MANAGEMENT
  - 3 ☐ closed with sutures
    - deep (size,type,#) ____________
    - skin (size,type,#) ____________
  - 2 ☐ closed with steri-strips
  - 1 ☐ left open
- DRAIN
  - 1 ☐ no 2 ☐ yes: ____________
- TOPICAL ANTIBIOTIC
  - 1 ☐ no 2 ☐ yes: ____________

DIAGNOSIS:

- DRESSINGS
  - 8 ☐ steri-strips 5 ☐ bulky
  - 1 ☐ xeroform 6 ☐ other: ________
  - 4 ☐ routine 7 ☐ none
- SPLINT
  - 1 ☐ no 2 ☐ yes: ____________
- MISC. SUPPLIES
  - 1 ☐ none 6 ☐ sling
  - 5 ☐ ace (size) ______ 7 ☐ crutches
- MEDICATIONS GIVEN IN ES
  - 1 ☐ Tet. Tox. 3 ☐ Penicillin
  - 2 ☐ Hypertet 4 ☐ Other: ____________
  - 5 ☐ none ____________
- PRESCRIPTIONS (Type, Dose, Schedule)
____
____
____
- DISCHARGE INSTRUCTIONS
  - 1 ☐ keep elevated 6 ☐ head sheet
  - 2 ☐ keep dry 7 ☐ med. use
  - 3 ☐ dressing change prn 8 ☐ other: ______
  - 4 ☐ change dressing ___ x/day
  - 5 ☐ return if signs of infection
  - ☐ return to work in (est.) ___ days
- FOLLOW-UP PLAN FOR WOUNDS
  - 1 ☐ disch. without f/u (return prn)
  - 2 ☐ ES clinic (or ES) in ___ days
  - 3 ☐ ___ days to clinic: ____________
  - 4 ☐ ___ days to pvt. MD: ____________
  - 5 ☐ admit to OR
  - 6 ☐ admit to floor
  - 7 ☐ admit to ICU
  - 8 ☐ transfer to ____________
  - 9 ☐ walked out
  - 10 ☐ other: ____________
- FORM COMPLETED BY
  - 1 ☐ M.D. 2 ☐ P.A. 3 ☐ student

REMARKS (additional Hx, P.E., X-rays, Lab, etc.):



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RESPONSIBLE PROVIDER (MD/PA)

that were recorded on the new form were traced through the laceration algorithm. A total of 2,003 nodes were encountered, of which 28 lacked the pertinent data, yielding a missing-data rate of only 1 percent. Eighty-five of the 99 cases (85 percent) contained complete data and were auditable (compared to 4 percent for the unstructured record). In other words, only 14 cases could not be audited because the physician had neglected one or more of the questions on the checklist. It should be possible to reduce this number to virtually zero by monitoring the checklist in conjunction with an ongoing case audit and educational feedback system.

The preceding section contained a quantitative description of the record-keeping practices of physicians in an emergency service. The laceration protocol was also used to evaluate the care provided by these physicians. This was accomplished by adding one further component to the node analysis described earlier. Each time the performance node was encountered, the data was checked to determine whether the physician followed the instructions contained in the node. If not, a "deviation" was recorded at that node by placing a circle around the symbol ("+" or "−") entered at that node. A "⊕," therefore, indicates that the physician recorded the pertinent data, but deviated from the protocol, whereas a simple "+" means that he recorded the data and followed the protocol's recommendation. Table 1 displays the node analysis for a selection of the 576 laceration cases. The actual sequence of nodes encountered by each patient is also displayed so that the pathway followed by a given patient through the algorithm can be traced. An analysis of "deviations" for the 576 cases revealed that, of the 2591 performance nodes encountered, 681 represented deviations. This yields a deviation rate of 26 percent (681/2591), or a "compliance" rate of 74 percent.

A node-by-node display for missing data is given in Table 2 and for deviations in Table 3. Deviation rates by individual provider are shown in Table 4 for one node, and show considerable variations from one provider to another.

Table 2: Analysis of missing data: laceration algorithm N = 576

Node #	*Description*	*# Nodes encountered*	*# Nodes with missing data*	*% Missing data*
9	Time since injury	478	264	55%
22	Location	270	0	0%
24	Dressing	236	63	27%
29	Tetanus immunization history	381	93	24%

Table 1: Case-by-case algorithmic node analysis

Patient	Node Number																																															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48
1	+	−	+						−	+	+		+	+	+	⊕	+		+	+	+	+		+	+		+		+	+			+		+			⊕						+				
2	+		+						−	+	+		+	+	−		+		+		+	+		+	+		+		+	+		+	+		+			+				+		+				
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Patient	Node Sequence																						
1	1	2	3	9	10	44	35	11	13	14	15	16	17	19	20	21	22	24	25	27	30	29	33	38
2	1	3	9	10	44	35	11	13	14	15	42	17	19	21	22	24	25	27	30	29	32	33	38	
3	1	3	9	10	44	35	11	12	14	15	42	17	19	21	22	24	25	26	30	29	33	38		
4	1																							
5	1	2	3	9	10	44	35	11	12	14	15	16	17	19	21	22	24	25	27	28	30	29	33	38
6	1	2	41																					
7	1	3	9	10	44	35	47	36	45	30	29	33	38											
8	1	3	9	10	44	35	11	13	14	15	42	17	19	21	22	24	25	27	30	29	33	38		
9	1	3	4	5																				

Table 3. Analysis of deviations: laceration algorithm N =576

Performance Node #	description	# of nodes encountered	# deviations	% deviations
8	leave wound open	24	10	42%
12	xylocaine, plain	116	30	26%
16	debride	143	78	55%
32	give tetanus toxoid	224	32	14%
41	obtain consult	30	1	3%

Table 4. Deviation rate by provider Node 32—Give Tetanus toxoid

Provider	Deviation rate
4	0% (0/7)
43	0% (0/21)
41	6% (1/18)
2	15% (2/13)
21	23% (3/13)
35	56% (5/9)
$x^2 = 19.1$	$p < .01$

Comment

The preceding section described how a clinical algorithm may be used to evaluate the process of patient care. The ultimate goal of a quality assurance system, however, is not merely to measure care, but to influence it for the benefit of patients, providers, and health care institutions. Achieving this goal requires that the results of evaluation be returned to the provider on an ongoing basis to inform him of possible patient management errors. Data from a given case should be keyed into the computer and traced through the algorithm shortly after the patient is seen, with results printed on a case-audit report sent to the provider. The provider returns the report with a written explanation of any deviations from the algorithm. Such a quality assurance system makes providers accountable to a set of agreed upon criteria. Although deviations should not automatically be viewed as "errors," they should be defensible. Deviations are expected to occur when unusual conditions concerning an individual patient require an alternative strategy, or when the algorithm contains a design flaw which was not previously recognized. The case audit report serves the function of continuing provider education, and also serves as a mechanism for ongoing improvement of the algorithm.

Clearly, an algorithm cannot function as a mechanical judge, making the final decision about the quality of care in an individual case. Rather, it serves as a screening device capable of separating usual or "standard" care from exceptional care which may prove to be either appropriate or inappropriate on closer examination. The branching logic of an algorithm provides an evaluative tool which recognizes the need for individualized therapy that depends upon a patient's clinical characteristics. At the same time, the tool represents a standard that may be applied to provider performance in an objective and unbiased fashion, thereby eliminating a major shortcoming of "implicit" peer-review methods.

Conclusion

The clinical algorithm is an appropriate tool to evaluate the process of ES medical care and to document the recordkeeping habits of providers. The unstructured ES medical record is an inadequate data source for such evaluative purposes, however, and only a small percentage of cases is sufficiently complete to permit auditing. Use of a condition-specific checklist greatly improves data completeness and, hence, the proportion of cases which can be audited. The rate of deviation from the algorithmic criteria varies greatly both among different nodes and among different providers. An individual case audit system, using an algorithm as the set of criteria, should form the basis of an efficient educational feedback system, since providers are appraised of both their individual case deviations and the correct management practices.

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The impact of Emergency Medical Services on mortality and morbidity: the case of pre-hospital acute cardiac care*

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The need for evidence of EMS impacts

When Congress renewed the Emergency Medical Services Systems Act of 1976 for three years and $210 million of Federal support of EMS at the state and local levels, it was clear that more evidence had been hoped for and would be expected next time on the impact of EMS intervention in reducing mortality and morbidity from the six high risk conditions mentioned in the original 1973 Act as particularly likely to benefit from EMS clinical and organizational interventions: acute cardiac, trauma, burns, poisonings, neonates, and behavioral emergencies (alcohol abuse, drug overdose, and psychiatric episodes). In first making the case in his 1972 Health Message to Congress for a Federal intervention program, President Nixon confidently asserted: ". . .improvement does not require new scientific break throughs, it only requires that we apply our present knowledge . . . By improving communications, transportation, and the training of emergency personnel we can save many thousands of lives. . ." More specifically, Congress in reviewing the rationale for the 1973 Act stated:

> "The numbers of preventable deaths and disabilities resulting from medical emergencies are grim evidence of the compelling need for action to deal with this problem. Estimates are that 15 to 20 percent of the deaths due to traumatic injury could be saved each year by improved EMS. This would result in 60,000 lives saved, based on estimates by the National Academy of Sciences. . . Heart attack is the leading cause of death in the U.S. In 1972, over 675,000 deaths were due to ischemic heart disease and myocardial insufficiencies. About one-half of the heart attack deaths oc-

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> curred within 2 hours of the attack and before the patient arrived at the hospital. The American Heart Association estimates that between 15 and 20 percent of pre-hospital coronary deaths could be prevented if proper care were administered at the scene and en route to an appropriate medical facility. According to the National Center for Health Statistics, there were approximately 68,000 deaths involving newly born infants in 1971. Many of these deaths could be prevented with an appropriate inter-hospital referral system to identify the newly born infant with a threatened chance of survival and to transport the infant to intensive care facilities. . . . It has also been estimated that 5000 deaths each year caused by drowning, poisoning, and drug overdoses, could be prevented if improved emergency medical services were provided immediately at the scene of the accident. These factors are convincing evidence of the importance of the establishment of systems to provide a network of comprehensive EMS systems throughout the Nation." (Senate Report 94–889, pp 11–12)

After $48 million of EMS spending under the National Highway Traffic Safety Program by the U.S. Department of Transportation between 1966 and 1973, a $73 million investment by DHEW on EMS before 1973, and after three years and $185 million of the 1973 Act, Congress examined available evidence on the mortality/morbidity consequences of EMS interventions but was forced to conclude: ". . .the hearings revealed that it is too early to determine and evaluate the long-range impact of the EMS system program. . . ." Ironically, in 1972 no caveats as to long-range impacts were entered and indeed the claim was confidently asserted that mortality reduction would be unequivocal and short-term. Thus, although in 1972 there appeared to be evidence on preventable deaths to establish the program, in 1976 there did not yet appear to be evidence on deaths actually prevented to justify retaining it. The program has, of course, been retained but this has been merely on the basis of Congress being ". . .impressed with examples of its successes including substantial cost savings to emergency medical patients."

It is important that the quality of evidence on EMS impacts be reviewed systematically for several purposes. First, if the Federal program is to be renewed for a second period of three years and legislation passed that strengthens it, the legislative and administrative review will begin in less than a year and it is important that it have available best present evidence on EMS impacts. Second, if the Federal program is to be terminated and replaced by local government funding, it is imperative that local government have available a systematic examination of what EMS interventions had which outcome impacts so that the lesser local money can be allocated more selectively. Third, whether or not this review indicates that EMS has reduced mortality it is desirable that this experience be used to improve evaluation methods so that other social initiatives can better and earlier be understood. For these reasons, a series of reviews is underway to examine the impact of EMS in each of the six clinical areas. This paper reports our findings with regard to pre-hospital acute cardiac care.

Cardiovascular disease

Clinical Parameters. Cardiovascular disease is the most common cause of death to persons age 35–64 and in the form of sudden cardiac death accounts for 300,000–400,000 deaths annually, or 20 percent of all deaths (Acton, 1973). It is important, however, to note the reduction in death rates from ischemic heart disease between 1968 and 1975 for both males and females (Shapiro, 1977). The generally used term "heart attack," denotes sudden cardiac death, acute coronary insufficiency, and acute myocardial infarction. Acute myocardial infarction is defined as a segment of heart tissue (myocardium) dying from inadequate blood supply, most frequently because of the obstruction of one of the coronary arteries supplying oxygenated blood to the heart muscle, which itself results from a buildup of fatty deposits on the artery walls (Cretin, 1974). Acute coronary insufficiency is an inadequate pumping of blood caused by an increase in the work imposed on the heart muscle (Lown, 1968). Sudden cardiac death is a general term describing unexpected death resulting either from an acute myocardial infarction or acute coronary insufficiency. About two-thirds of all deaths resulting from arterio-sclerotic heart disease are sudden (Kuller et al, 1971).

The severity of the acute incident varies from the unnoticed infarct to a massive infarct resulting in sudden death. Symptoms and signs may include altered enzyme levels, pulmonary congestion, peripheral constriction (manifesting as cold, clammy hands), cyanosis (purplish coloration of skin due to deficient oxygenation of the blood), diaphoresis (profuse sweating), and shock (Killip, 1968). There are at least two mechanisms of death related to acute myocardial infarction. If the heart is extensively damaged by the infarction, pump failure will occur depriving vital organs of an adequate supply of oxygenated blood, with death resulting. In contrast, death may result from electrical failure triggered by a change in the chemical balance of the heart, even when damage to the heart muscle is minimal (Acton, 1973). While it is believed that at least half of all myocardial infarction deaths are electrical failures (Pantridge and Geddes, 1967), it is also inferred that the vast majority of pre-hospital deaths are electrical (Acton, 1973). Electrical disturbances ("arrhythmias" or "dysrhythmias") cause variations in the heart's pumping action, reducing its pumping effectiveness. Mild arrhythmias include extra or premature beats (extrasystole), a faster than normal beat (tachycardia) or an abnormally slow rhythm (brady-arrhythmia). In the hours following an infarct, death is more likely to result from serious arrhythmias such as ventricular fibrillation or asystole, than from the mild ones. Ventricular fibrillation is an "incoherent disorganized electrical activity which induces the heart to flutter in an uncontrolled manner" (Sherman, 1977) so that the heart is unable to pump effectively. Asystole refers to the absence of any heart beat at all. For both ventricular fibrillation and asystole oxygenated blood is cut off from the brain resulting in permanent brain damage and death if intervention does not occur within a few minutes (Cretin, 1974).

Patient Delays. In outlining the clinical parameters and natural history of sudden cardiac deaths, it is important to note the likelihood and different forms of delay by the patient in summoning and receiving appropriate medical care. Just as the previous clinical description laid the basis for the three major pre-hospital EMS interventions (defibrillation of electrical disturbances, CPR and anti-arrhythmia medications), the following description of patient delay serves to outline the organizational changes that may result from EMS implementation that may reduce the probability and amount of patient delay. Thus, following the onset of a cardiac emergency:

- the victim may delay in interpreting the symptoms as cardiac symptoms
- the patient or bystanders may not know how to telephone for ambulance care
- the ambulance agency may not dispatch an ambulance
- the ambulance may delay in arriving at the patient's location
- the ambulance may delay in arriving at the hospital CCU.

Simon et al (1972) have documented the prolonged delays in correctly interpreting chest pain, a widely-publicized symptom which in fact is present in only half of those experiencing prodromal symptoms. Grace (1974) has shown that patients are often unable or reluctant to recognize the meaning of these symptoms, or reluctant to call for medical assistance because of a lack of confidence in clinical intervention. Patient delay is related inversely to the patient perception of severity (Hackett and Cassem, 1969); paradoxically, patients with prior histories of the symptoms often delay longer (Moss and Goldstein, 1970). In addition, although discussion with relatives and friends may reduce delay, discussion with family physicians may add to the delay and reinforce the patient's initial misinterpretation of the symptoms (Grace, 1974; Hackett and Cassem, 1969; Kuller, Cooper and Perper, 1973). While acknowledging difficulties in comparability between studies of patient delay due to definitional inconsistencies, Sherman (1977) presents useful aggregate data on patient delay suggesting an average delay in deciding a course of action of at least two and a half hours, and mean hospital arrival times averaging up to 16.9 hours.

These factors readily suggest the potential need for EMS organizational interventions such as patient education campaigns, ambulance central access and dispatch points, transport protocols, etc. Nevertheless, it is essential in the light of somewhat enthusiastic estimates of how many lives pre-hospital interventions can salvage, to recognize that many myocardial infarction victims do not survive through the entire sequence from symptom recognition to CCU admission. Sixty-one percent of sudden arterio-sclerotic heart disease deaths in Baltimore occurred outside the hospital while 34 percent occurred instantly (Kuller et al, 1971 and 1973). Of 64 cardiac deaths in San Francisco, 27 were instantaneous (Friedman et al, 1973). In only those few cities with the ability to deliver pre-hospital care in less than 3-4 minutes and with large numbers of citizens proficient in cardiopulmonary resuscitation can a reasonable proportion of such "instantaneous deaths" be considered salvageable.

EMS and pre-hospital cardiovascular care. From a historical perspective, the technical knowledge base for pre-hospital cardiovascular care may be said to have begun with the reversal of ventricular fibrillation in a dog at the turn of the century (Lown 1968). In 1947 Beck and others succeeded in the electrical reversal of ventricular fibrillation in humans (Lown 1969) while in 1956 Zoll showed that electric current could effectively defibrillate even across a closed chest. Kouvenhoven in 1969 showed that external cardiac compression could maintain blood flow after the heart had arrested, thus providing the basis for Cardio-pulmonary Resuscitation (CPR). Together with the development of cardioversion as a safer method of electrical defibrillation, and improvement in electronic instrumentation for continuous audio and visual monitoring of heart rhythms and their transmission by radio (that is, telemetry) the technical basis existed for intervention in pre-hospital cardiac emergencies.

The implementation of pre-hospital coronary care has as its milestones the introduction of special ambulances for cardiac patients in Moscow in the 1950's (Chazov, 1968), and the concept of the Mobile Intensive Care Unit (MICU) developed by Pantridge and Geddes in Belfast. In January 1966, the latter introduced a program in "an attempt to prevent deaths from cardiac arrest occurring soon after the onset of symptoms and in an attempt to assure safe transport of the patient with myocardial infarction." The Belfast program aimed at bringing the full resources of the hospital CCU, including physicians, to the patient wherever he was. Intervention was, however, limited to resuscitation. In the U.S., the only equivalent (in the sense of being staffed by physicians and nurses) of the Belfast program was that established by Grace at St. Vincent's Hospital in New York City (Grace and Chadbourn, 1969). In addition to resuscitation, monitoring, and defibrillation, the New York City ambulance program used such antiarrythmic drugs as atropine and lidocaine intramuscularly and intravenously if minor arrhythmias were detected on the ambulance electrocardiograph in an attempt to prevent escalation to a more serious arrhythmia.

While the Moscow, Belfast and St. Vincent's ambulance programs were special purpose units limited only to cardiac cases, the more prevalent approach subsequently was the general purpose MICU. First developed in the U.S. by Nagel in the Miami area (Nagel, 1970), an MICU is generally situated within a fire department, staffed by highly trained paramedics and emergency medical technicians, with telemetry-radio capacity to obtain electrocardiograms at the scene and transmit them to the base hospital where they be read by the physician. Cardiovascular intervention includes defibrillation upon command from the hospital physician (or in compliance with a predetermined protocol) and administration of antiarrhythmia medications. Such Advanced Life Support MICU programs have been developed and described in many cities, including Seattle (Baum et al., 1974), Los Angeles (Andrews et al, 1975), Illinois (Boyd et al, 1973), Charlottesville (Crampton et al, 1975), Nassau County (Lambrew, 1974), and Chicago (Sherman, 1977).

The staff in MICUs are paramedics trained to the advanced life support level. This is the highest level of ambulance attendant training, the lowest one being training in first aid. The intermediate level is the EMT trained according to the U.S. Department of Transportation approved 81-hour course in basic life support. With regard to cardiovascular pre-hospital care, basic life support consists of opening and maintaining an airway for breathing, providing artificial ventilation, and artificial circulation by external cardiac compression, that is, cardiopulmonary resuscitation, or CPR. The highest level, that of the paramedic (of which the Department of Transportation estimates there are 8,000–10,000 in the U.S. at present) requires anywhere from 100–1400 hours training. These paramedic programs vary substantially and until recently no attempt has been made at curriculum standardization. In January 1975, the President's Intragency Committee on Emergency Medical Services recommended a standard curriculum for paramedics to be endorsed by all agencies. In July the U.S. Department of Transportation contracted with the Department of Anesthesiology at the University of Pittsburgh School of Medicine to prepare the curriculum and define the knowledge and skill objectives required for paramedics. The substance of the curriculum was completed by July 1976 and received federal endorsement as well as that of several state legislatures. The recommended paramedic skills include:

- History-taking and physical examination
- Assembly of intravenous equipment, venipuncture, and initiation of peripheral intravenous lines
- Application and appropriate use of military antishock trousers
- Calculation and administration of correct dosages of intravenous, intramuscular and subcutaneous medications
- Airway management with a variety of adjuncts, including oropharyngeal and nasopharyngeal airways, pocket mask, bag-valve mask, demand valve and endotracheal intubation
- Oropharyngeal, nasopharyngeal, endotracheal and tracheostomy suctioning, with sterile technique where appropriate
- Direct laryngoscopy
- Electrocardiographic monitoring; recognition and management of 18 dysrhythmias
- Cardiopulmonary resuscitation, including defibrillation and use of resuscitative drugs
- Immobilization of an injured spine
- Hemorrhage control by direct pressure, pressure point control, tourniquet and military antishock trousers
- Care of a variety of soft tissue injuries, including lacerations, impaled objects, avulsions and amputations
- Care of burns
- Immobilization of musculoskeletal injuries with various commercial and improvised devices
- Management of normal complicated obstetric events
- Management of acute pediatric problems
- Management of acute psychiatric problems
- Proficiency in basic rescue, including vehicle stabilization, access, disentanglement and extrication.

It would, however, be incomplete to mention only MICU Programs (and their component telemetry, EMT training, and anti-arrhythmia drugs) as the sole characteristics of the EMS systems development likely to have an impact on pre-hospital cardiovascular care. There have been other interventions and although they have been less publicized or evaluated than MICU's, they are believed by many to have had an important effect. These additional interventions include:

- The introduction of a single access telephone number (911 or Enterprise and inward WATS line) to facilitate requests for ambulance care
- Introduction of a central dispatch point within a region for all ambulance units to reduce response time
- Mass media patient education campaigns on symptom recognition and how to request assistance
- Training of the lay public (as in the Medic 2 program in Seattle, Washington) to perform CPR (Cobb, et al, 1975)
- Development and dissemination of pre-hospital cardiac treatment protocols
- Development and dissemination of cardiac transport and inter hospital transfer protocols
- Categorization and regionalization of hospital cardiac care

These interventions have been variably introduced throughout the country even though they are mandated program requirements under the Emergency Medical Services Systems Act of 1973 and 1976. They are also features strongly encouraged by the Robert Wood Johnson Foundation in the 44 EMS regional communications systems it funded. Other interventions, although noteworthy as having potential impacts, are not sufficiently widespread to merit discussion at this stage. They include free-standing life support stations, self-administration of anti-arrhythmia drugs by high risk patients, equipping police cars with electrocardiographs and defibrillators, etc. Similarly, primary prevention strategies (such as changes in diet, exercise, lifestyle) will not be further considered since they are not seen as EMS interventions.

Evaluation of EMS effects. The shift of programmatic interest from hospital to pre-hospital intervention for cardiac care is generally based on the belief that little additional improvement is likely for the hospital phase. Sidel (1969) presents the argument:

> ". . .Coronary Care Units have been successful in reducing the in-hospital case fatality rate from about 30 percent to about 20 percent . . . There is ample documentation that only about one third of patients who die after a heart attack reach the hospital alive . . . Since there might be at best 33 percent of those patients otherwise destined for death who currently reach the hospital alive, it follows that the upper limit of mortality reduction, even given full implementation of the in-hospital CCU concept, is at best 10 percent. . . . If coronary death is to be reduced, the problem must be dealt with . . . before the patient reaches the hospital."

Against this background there are aggressive claims as to the effect of EMS intervention on pre-hospital cardiovascular care and particularly of MICUs on the number of sudden cardiac deaths. Pantridge (1970), on the basis of four years experience, estimated that his MICU program would reduce the myocardial infarction mortality rate from 35.5 percent to 25.8 percent. Based on this and other projections, it has been estimated that MICUs in the U.S. would save 35,000–50,000 lives (Cretin, 1974).

In the face of these optimistic claims, it is particularly important to be cautious and realistic. Similar claims have been made for CCU's and doubted by others. Thus, in 1969 Lown et al concluded:

> "so numerous are the differences in diagnostic criteria of acute myocardial infarction, in composition of populations under study, in rapidity of admission to the CCU, in therapeutic policies and in data presentations that no final conclusions are as yet possible."

While in the same year a RAND study came to the opposite conclusion:

> "all other things being equal, an MI patient has a considerably better chance of survival when treated in a CCU than when treated in a regular hospital ward." (Rockwell, 1969)

Some have argued for more moderate claims for MICU impact on sudden deaths by noting that many such deaths are so sudden as to "escape medical feasibility" (Goldstein et al, 1972). Thus, Rockwell (1969) notes with regard to hospital CCU's:

> "When ventricular fibrillation occurs, the condition must be treated within 240 seconds after onset to prevent irreversible damage to the patient (e.g. brain death). If a physician is not already at the patient's bedside, there simply isn't enough time to summon him before administering treatment."

This constraint is, of course, likely to be greater out-of-hospital than in-hospital. Adgey et al (1968) notes that the Belfast MICU was able to apply resuscitation to less than one-half of the 126 victims in cardiac arrest within these 4 minutes. In addition, patients, as we have noted, may not recognize cardiac symptoms, or for other reasons may not summon an ambulance; patients may and do delay requesting help beyond the point of potential EMS impact. Cooper et al. (1969) are even more cautious and state that "the only victims who would be benefited by the MICU are those who would otherwise have died between the time of the ambulance arrival and the delivery at the hospital."

These and other considerstions have led Kuller (1973) in his examination of sudden deaths in Baltimore to agree with the conclusions of the Framingham Study (Kannel et al. 1967):

> "Because of the nature of this distressingly common, insidious, and highly lethal disease (coronary heart disease) it is clear that further innovations in treatment, while they may save many individual lives, cannot substantially reduce the over-all mortality from this leading cause of death. Only a preventive approach can accomplish this."

Evaluative criteria for EMS impact studies

Although the justification for creating the EMS program was almost entirely outcome-oriented (it would save lives and reduce morbidity) the justification for continuing it has been limited to input and process parameters (it has made resources available and they have been used wisely and widely). Nevertheless, it is reasonable to define program impacts as outcomes and to pursue the initial claims to see whether they have been fulfilled. We have reviewed the available literature with certain minimal criteria in mind that must be observed by a study before it can be regarded as an adequate evaluative description of a program impact. We have described and elaborated these criteria elsewhere (Gibson, 1977) and it is only necessary to reiterate them here as including:

- Standardized methods to conceptualize and measure the independent (EMS program intervention) and the dependent (impact) variables.
- Measurement of the impact parameters before and after the introduction of the intervention (the program variable) and a sufficient number of "before" measures to establish whether there was (and the nature of) a secular trend in the impact variable.
- Measurement of the dependent variable in both the treatment group and a control group that is (at worst) demonstrably similar in every respect save for the treatment to the treatment group and, at best, that is equivalent by reason of having being randomized.
- A study design that measures the impact of separate EMS interventions rather than aggregate "package" effects.
- The clear identification of a relevant study population in which there is shown to be a relationship between process and outcome.
- A statement as to population-based changes in mortality or morbidity for a region rather than merely changes in a treated population from one facility.
- An ability to disprove the possibility that the observed results could have been caused not by the hypothesized treatment effects of the variable under study but by other exogenous factors such as selection biases, etc.
- A form of the EMS intervention being evaluated which is modal and typical of its common usage in the U.S.

Diagram 1 indicates the analytic framework and the classification of the independent, intervening and dependent variables used in the present literature review.

EMS Effects on pre-hospital cardiovascular care

The above criteria were used to assess the available literature on EMS effects on pre-hospital cardiac care. This literature was defined as any English language empirical and original study reporting cardiac-relevant results attributed to pre-hospital EMS intervention.

Adgey (1969) described 55 patients in cardiac arrest on whom pre-trial resuscitation was attempted and from this, estimated future mortality reduction. Graf et al (1973) examined the first three years' experience of the the Los Angeles pilot coronary care ambulance and reported that, of 186 patients on whom resuscitation was attempted for cardiac arrest between 1969 and 1972, 35 (19 percent) were discharged live from the hospital. Graf also reported a lower mortality rate for vehicles staffed by nurses than for those with paramedics. Both of these studies lack before/after measurement and a control group and thus are unable to make statements about the effects of EMS (as opposed to exogenous variables) on mortality. Similar studies have been conducted by Cobb et al (1975) on Seattle ventricular fibrillation victims. This latter study has the largest published series of patients: 1106 with ventricular fibrillation from the first 51 months of MICU program operation; two hundred and thirty four (21 percent) were discharged from hospital alive although this rate was 11 percent for the first 2 years of the program and 22 percent for the second 2 years. The author attributes this change to improvements over time in the effectiveness of the Seattle Medic 1 program although without a control group and pre- and post-intervention measurement it is impossible validly to make this claim.

One study does have pre- and post MICU data and a (non-randomized and, therefore, non-

Diagram 1: Analytic framework for assessment of EMS effects on prehospital cardiovascular care

Independent variables—EMS effects	Intervening variables (to be controlled for)	Dependent variables: Prehospital cardiovascular care
• MICU (defibrillation, CPR anti-arrythmia medication)	• Clinical severity	• Mortality rate of MICU treatment group
• Telemetry	• Geographical location	• Mortality rate of CCU treatment group
• Single access ambulance number	• Patient co- and prior morbidity	• Mortality rate of geographic area
• Ambulance central dispatch	• Age and sex structure of patient groups	• Mortality status at CCU arrival
• Education campaigns on symptom response		• Mortality status at hospital discharge
• Pre-hospital treatment protocols		• Mortality status at 12 months post-discharge
• Evaculation and transfer protocols		• Mortality of survivors
• CPR training of public		• Delay between symptom onset and CCU arrival
• Categorization/regionalization of cardiac care		• Receipt of appropriate prehospital diagnostic/therapeutic procedure
		• Transport of patients to appropriate hospital facilities
		• Availability of pre-hospital cardiac resources

equivalent) control group and it is generally regarded by EMS program managers as the "best" study available: Crampton et al's 1975 report on the physician-staffed Mobile Coronary Care Unit (MCCU) in Charlottesville, Virginia. Mortality from acute myocardial infarction at a University Hospital *increased* from 16.7 percent before MCCU implementation to 19.3 percent after, whereas over the same period (1966–70) at a community hospital without an MCCU, acute myocardial infarction mortality *decreased* from 23.1 percent to 15.8 percent. As Sherman points out (1977), Crampton et al. do not discuss this comparison but pool the data and report only on the geographic area as a whole, erroneously claiming that a 14.8 percent decrease in average annual coronary death rates "directly resulted from" the MCCU. Other limitations to the study and the conclusions to be drawn from it include:

- The MCCU was physician-staffed and therefore more an extension of the CCU into the community than the paramedic MICU common in the U.S.
- Clinical data on the incidents is not given although three "saved" patients are reported as not having coronary events at all.
- Community cardiac mortality was falling prior to the study period and may have been independent of the program.
- There is an unreasonable concentration on death occuring in the ambulance at the expense of any examination of hospital and community deaths.

Several studies have been reported on the Los Angeles MICU program. Andrews et al (1975) compared the effectiveness of MICU with that of a traditional ambulance across 22 broad illness categories, one of which was "cardiovascular." Survival rates upon arrival at the emergency room for cardiovascular cases were identical for MICU and traditional ambulance cases, although a 20 percent difference in long-term survival was noted in favor of MICU cases. (It is likely, however, that there were selection biases which produced prior differences between the two groups so great as to prevent any reasonable claim for an MICU treatment effect. MICU and traditional ambulances were dispatched differently and according to different criteria, served different populations and were stationed in different locations; it is altogether possible that the case severity was different.) Diamond et al reported that 50 of 100 cardiac arrests transported by paramedics between July 1974 and May 1975 in Los Angeles were discharged live from hospitals.

In Miami, Nagel et al (1970) have collected data on all patients with ventricular fibrillation treated by paramedics. Of 301 patients treated in 42 months, 14 percent were discharged live from the hospital with a mean survival time of 13 months thereafter. Richupann and Anderson (1975) in their studies in Jacksonville, Florida, found a higher mortality rate for ambulance-transported myocardial infarct patients than for non-ambulance-transported myocardial infarct patients and fail to mention selection biases as a probable cause. They also report a time series of age-adjusted myocardial infarct death rates before and after the introduction of the "EMS System." Pantridge (1970) compared the mortality rate of his Belfast MICU patients and found it to be half of rates reported in the literature for CCU patients, although he fails to discuss selection biases.

In Nottingham, England, Hampton et al reported on an MICU which during a 20-month period was staffed on alternative days by specially-trained ambulance personnel or such personnel and a physician. Ambulance staff were trained to use (and had available) a defibrillator, a respirator, and pain relieving medications. The physician had diamorphine, a full range of antiarrhythmic drugs, and equipment for endotracheal intubation and ventilation. The cardiac ambulance with a physician treated 126 patients and without the physician treated 330 patients while both groups of patients were remarkedly similar with regard to sex, age, previous heart attacks, delay between symptom onset and calling the ambulance, symptoms and signs both pre-hospital and at arrival at the hospital, and severity of heart attack. Because of these similarities, the outcome differences (if any) may then be reasonably attributed to the presence of a physician who could administer intubation and anti-arrythmic drugs (procedures which in the U.S. are seen as distinguishing paramedics from EMTs). In fact, there were no differences in outcome. Pre-hospital mortality was 19 percent for the cardiac ambulance with the physician and 20 percent without; hospital mortality was 20 percent for the cardiac ambulance with a physician and 21 percent without. Indeed, the overall mortality (pre-hospital and hospital) for all cardiac ambulance patients was similar (43 percent) to that for patients transported by routine means (46 percent). The authors conclude:

> "These results suggest that, no significant benefit is gained by using medically trained staff on a cardiac ambulance, and second, that it is doubtful whether there would be any significant benefit from training ambulance crews to medical standards of drug administration and intubation .... Even the most enthusiastic proponents of cardiac ambulance services can produce little evidence of any reduction in community mortality; any claims of low mortality resulting from a cardiac ambulance service can only be considered valid if the results attained by the routine service at the same time are provided."

A substantial flaw in most studies of pre-hospital cardiac interventions is a lack of concern with false vs. true positives (that is, the population of those receiving the intervention who had no need for it) and the yield in terms of appropriate interventions. Pozen et al (1977) in their study of telemetry in the Baltimore region are among the few to deal with both issues. Twenty-two months experience of two telemeterized ambulances staffed by paramedics with back up from a nearby university affiliated municipal hospital with two-way radio and ECG write-out equipment used by the house staff to provide ECG interpretation and medical support for ambulance crews. Even though the ambulance, its equipment and crew were specially prepared and intended for pre-hospital cardiac intervention, only 22 of the 7654 patients transported by both ambulances received pre-hospital intervention based on telemetry. Of the 22 only six were alive three months later. The outcome yield therefore was six out of 7654. Further, two cardiologists reviewed the medical records of 1771 consecutive patients transported by both cardiac ambulances over a six-month period, and found that only 71 patients had acute ischemic heart disease. "That is, only four percent of the patients had the disease for which the system was specifically designed . . ." and 96 percent did not.

Finally, in a relatively sophisticated research design using a time series, Sherman (1977) examined death and survival from myocardial infarction in four suburbs of Chicago over a 65-month period during which an MICU system was introduced. In two of the four communities the mortality rate decreased after MICU system implementation and in two it did not. There was, however, no non-intervention control community included as an indicator of secular trends in mortality.

Summary and conclusions

The literature has been reviewed to identify English-language empirical and original studies reporting cardiac-relevant results attributed to pre-hospital EMS interventions. Eighteen studies were identified of which 14 were conducted in the U.S. many authors (notably Pantridge, Cobb and Crampton) have reported several times on the same series of patients, or multiply in the process of accumulating the same series. In these cases, only one such study has been reviewed except where a different independent or dependent variable has explicitly been examined. These studies are summarized in table 1. No single study unequivocally documents that pre-hospital EMS interventions reduces cardiovascular mortality or morbidity. The studies were assessed by means of five evaluative criteria. Of the 18 studies, only two report data on the impact variable for periods before and after the introduction of the EMS intervention being examined, only two had a control group to compare with the treatment group, and for only nine of the 18 was the form of the pre-hospital EMS intervention to all comparable to its present usage in the U.S. In only two of the 18 studies was any successful attempt made to disprove the rival hypotheses that factors other than

Table 1: Evaluative summary of English-language original studies on EMS interventions and pre-hospital cardiovascular care

Authors	EMS interventions	Impact variables	Study population	Before/After measure?	Control group?	Modal intervention?	Rival hypothesis disproved	Population based rate change?	Results
Adgey 1969	CPR within 4 minutes of arrest	Survival at hospital admission	61 patients with pre-hospital VF	No	No	No	No	No	No survival if CPR after 4 minutes, 39 of 48 patients survived with CPR within 4 minutes
Adgey 1972	MICU in Belfast	Survival at hospital admission and discharge	2753 MICU runs over 4 years	No	No	No	No	No	"reduces . . . mortality . . . :
Andrews 1975	MICU in L.A.	Long-term survival and at ER arrival	"Cardiovascular" cases treated in MICU vs traditional ambulances	No	Yes	Yes	No	No	No difference in survival to ER but 20% less mortality in long term for MICU vs traditional ambulance
Baum 1974	Central access/dispatch in Seattle, public education	Survival at 418 days (average follow-up)	146 patients resuscitated over 2 years from pre-hospital VF and discharged live from hospital	No	No	Yes	No	No	"13 of 146 died; out of hospital VF . . . treatable"
Carveth 1975	MICU at college football stadium	"long-term resuscitation"	18 cardiac patients seen during 46 home games over 8 years	No	No	No	No	No	Out of 18 cardiac patients, 14 arrested and 12 were resuscitated and 7 survived "long-term"
Cobb 1975	As above	Survival at 437 days (average) follow-up	231 patients resuscitated over 51 months from prehospital VF and dischared live from hospital	No	No	Yes	No	No	72 of 234 died
Cobb 1976	MICU, public education, central access, rapid response	"Lives saved"	1106 patients with VF on arrival of MICU over 4 years	No	No	Yes	No	No	57 of 511 patients in first year discharged live from hospital and 137 of 595 in 2nd year
Crampton 1971	MICU in rural Va., central access, public education	Deaths in ambulance, pre-hospital coronary deaths	476 MICU runs March 1971–Dec. 1973	Yes	No	No	No	Yes	"Pre-hospital coronary death rate fell 26 percent and ambulance coronary death rate 62 percent."
Czachowski, 1976	MICU in rural Pennsylvania	Survival at hospital admission and discharge	225 patients cared for by MICU over 8 months	No	No	No	No	No	Of 225 patient's, 8 definite saves (3 long term, 5 short term) and 7 possible saves
Diamond 1977	Resuscitation by L.A. paramedics	Survival at hospital admission and discharge	2152 paramedic rescue runs	No	No	Yes	No	No	Of 120 cardiac arrests, 24 admitted live to CCU and 16 discharged live
Grace 1969	MICU in New York City	Unspecified survival	161 MICU runs	No	No	No	No	No	"One of 161 runs only unequivocal life saving episode . . . It is the feeling of the authors that considerable good can be done."
Gearty 1971	MICU in Dublin	Death in ambulance	1973 cardiac ambulance transported patients	No	No	Yes	No	No	No deaths in ambulance

Table 1: Evaluative summary of English-language original studies on EMS Interventions and pre-hospital cardiovascular care—continued

Graf 1973	MICU in L.A. County	"Long-term resuscitation"	1240 transported patients	No	No	No	No	No	Of 186 resuscitation efforts, 85 patients admitted live and 35 discharged live.
Hampton 1977	Physician staffed MICU in Nottingham, England	Pre-hospital and hospital mortality	1072 patients with heart attacks	No	Yes	Yes	Yes	Yes	Pre-hospital mortality 19 percent for patients brought by M.D. staffed cardiac ambulance and 22 percent for patients brought by cardiac ambulance without M.D.; overall mortality 43 percent for cardiac ambulance patients vs 46 percent for routine ambulance patients.
Honick 1974	Nurse staffed MICU in Oklahoma	Survival on hospital admission	3581 runs over 4 years	No	No	Yes	No	No	103 of 170 patients with V.V live on CCU admission
Liberthson 1974	Pre-hospital EMT defibrillation in Miami	Survival at hospital admissions, discharge and 12 month follow-up	301 patients with pre-hospital VF detected by Miami rescue units	No	No	Yes	No	No	42 of 301 discharged live from hospital
Nagel 1970	MICU in Miami	Transmission failures, response times	146 telemetered patients over 2 years	No	No	Yes	No	No	"MICU . . . very fast response . . . immediate availability . . . lower costs . . . higher utilization . . . community acceptance."
Pozen 1977	MICU and telemetry in Baltimore	Survival at 3 months	7654 patients transported by 2 MICU's over 22 months	No	No	Yes	Yes	No	Of 7654 patients 22 received pre-hospital cardiac interventions and only 6 of those survived to 3 months. Of 1771 transported patients whose medical records were reviewed by 2 cardiologists, only 4 percent had acute ischemic heart disease.
Sherman 1977	MICU in 4 Chicago suburbs	Survival to hospital discharge	5000 hospital medical records (for unit patients) of which 30 percent had sufficient data						MI mortality rate reduced in 2 of 4 communities.

the EMS intervention could have caused the noted change attributed by the investigator to EMS interventions, and only two of the 17 studies made statements as to effects upon changes in population-based mortality rates. It should be noted that the more evaluative criteria a study satisfied, the less likely it was to indicate a beneficial EMS impact on mortality while the fewer of these it met, the more likely it was to claim an EMS impact.

Because of these methodologic deficiencies it is unfortunate but true that we are no nearer now than a decade ago to answering the question raised in the 1960's and early 1970's about the effectiveness and yield of mobile coronary care. Thus, we still lack evidence called for by Cooper, Steel and Christodoulou who commented in the late '60's:

> "Before general implementation of MCCU's can be recommended several issues need to be clarified. The original investigators have shown the feasibility of the mobile unit, and their descriptions contain anecdotal accounts of lives saved. It is apparent, however, that the overall value of these units as an alternative health service has not yet been established. The most critical question in the MCCU concept is how many lives such an innovation would save. Of the 250,000 annual out-of-hospital deaths, 90,000 are victims over the age of 75. Another 90,000 persons are less than 65 years of age. How many actually seek help? Obviously, those who die without ever seeking aid could not benefit. How many die because adequate help was too slow in arriving? In many communities, this figure must be low. A critical analysis of the situation reveals that, considering the MCCU alone, the only victims who would currently be benefited are those who would otherwise have died between the time of arrival of the ambulance and delivery to the hospital. Some preliminary data indicate that in some communities, death in transit is quite rare. Further documentation of the number of ambulance deaths and the frequence of treatable serious arrhythmias occuring in transit is needed. . . . Because of the basic emergency facilities available in some communities, it is possible that the implementation of these other improvements, without the mobile unit, would result in essentially the same lifesaving benefit but without the associated cost."

It should be emphasized that the issue here is not merely one of documenting something that everyone recognizes as true by producing evidence confirming that mobile coronary care is effective, but instead the more basic one of refuting claims that it is not effective. Lown, (1969) for example, doubts that an MICU can be deployed quickly enough for intervention (whether effective or not) to be feasible for most coronary deaths:

> "A more fundmental criticism of mobile units relates to the nature of coronary death. This is clearly indicated by the studies in Belfast. McNeilly and Pemberton found that 60% of all coronary deaths occur outside the hospital. Of 596 such fatalities occurring within the community during the course of a single year, only 18% survived for more than one hour after onset of the terminal attack. Thus in the majority of coronary deaths little time is available for mobilizing an adequate medical response."

Lewis and Criley also point out the substantial patient delay in summoning assistance as a fundamental limitation to the effectiveness of MICU's in their mid-decade assessment.

> "The pioneering efforts of Pantridge and others offered the first encouraging results in reducing the large number of deaths from pre-hospital ventricular fibrillation (VF). Subsequently, a number of so-called coronary ambulances or mobile coronary care units (MCCU) were developed. Such categorical rescue units have not fulfilled early expectations. The number of lives saved has been small, the initial and operational costs high, and the utilization low. These results are not surprising if one considers the fact that most patients with acute myocardial infarction (AMI) wait several more hours before seeking medical assistance; if cardiac arrest should occur, many minutes after elapse before resuscitation is begun."

Tjoe and Luria (1972) take this point further and comment that the role of transportation time is insignificant compared with patient delay. After considering MICU's in Cleveland compared with routine ambulance units they state:

> "There appeared little significant difference in effectiveness when the greatest cause for delay, the patients' failure to promptly seek medical help, was considered. Because of significant delays, especially in decision time, there presently appears little need for emphasis on costly and professionally time consuming mobile coronary care units."

It is, therefore, not possible to draw any substantive conclusions about the relationship between EMS and pre-hospital cardiovascular care because of the grave methodologic deficiencies in the studies reviewed. Mortality rates from acute myocardial infarction (specifically, the proportion discharged live from the hospital) vary greatly between areas with MICU programs and also fluctuate substantially over time within these areas.

Only the following methodologic conclusions about existing studies may reasonably be drawn:

- Most studies have assessed EMS effects only on cardiovascular mortality rates and unreasonably downplayed input and process parameters and impact variables.
- Most studies lack a control group that is equivalent by reason of being randomized; and even when non-equivalent control groups have been used, selection biases are sufficiently great that unequivocal statements as to treatment effects cannot be made.
- Often pre- and post-intervention measurement have not been made, and when they have the time-series may be so short, unstable or sensitive to exogenous variables as to mask treatment effects of EMS.
- The program component of EMS has been examined in terms of effect on pre-hospital cardiovascular care is almost entirely limited to MICU/paramedics with little systematic assessment of other EMS organizational and clinical interventions.
- Studies insufficiently use comparable definitions or data collection procedures or define the clinical cases involved, so that it is often difficult to determine whether the cases were clinically similar.
- Studies often fail to assess the independent effect of a separate intervention but only measure the gross "package" effects of a set of overlapping clinical and organizational interventions.
- Studies fail to examine and disprove the possibility that the observed results could have resulted not from a hypothesized treatment effect of the variable under study but other exogenous factors.

If the case is to be made to, and believed by, Congress that pre-hospital EMS reduces cardiovascular mortality and morbidity, it cannot be based on existing studies. New and substantially better investigations must be undertaken if such a relationship is to be examined and documented.

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